Response of

the Pharmaceutical Services Negotiating Committee

to

the Department of Health consultation on

Pharmacy in England:

Building on strengths – delivering the future – proposals for legislative change

November 2008

Executive Summary

1. The Pharmaceutical Services Negotiating Committee (PSNC) welcomes the opportunity to respond to the Department's consultation on Pharmacy in England: Building on strengths – delivering the future – proposals for legislative change.

2. The Pharmacy White Paper is an important part of the strategy for the future of the NHS, recognising the potential for pharmacists to provide a wider range of services to the public, building on their existing strengths and expertise in medicines. To realise the benefits of the proposals, the arrangements under which pharmacy contractors provide pharmaceutical services must encourage investment.

3. Robust Pharmaceutical Needs Assessments (PNAs) developed in partnership between Primary Care Trusts (PCTs), Local Pharmaceutical Committees (LPCs), pharmacy contractors and the public could form the basis of a market entry test for pharmacies. The PNA must be closely aligned to the Joint Strategic Needs Assessment. An early evaluation would be needed to alleviate any concerns about this radical overhaul of the current system.

4. As PCTs develop further their commissioning responsibilities, they need access to tools that encourage and reward high quality service as well as dealing with those who fail to achieve the required standard.

5. PSNC supports the introduction of a vetting regime for pharmacists who provide NHS pharmaceutical services, along similar lines to that which applies to the other healthcare professionals providing services under the NHS. The vetting arrangements should allow movement across the home country boundaries.

6. The exemption from the control of entry test for pharmacies offering to provide NHS pharmaceutical services for at least 100 hours per week has provided improved access in some areas, but this benefit is outweighed by the additional costs to the NHS of substantial additional numbers of pharmacies that do not increase accessibility, and the detriment caused to other pharmacy contractors. A PNA based market entry test will remove the need for the exemption, but until the PNA regime has been introduced, a moratorium should be imposed to prevent further damage to the network.

7. The market entry test for dispensing doctors as set out in the 2005 Regulations was introduced with the full support of PSNC and representatives of dispensing doctors and followed a considerable period of negotiation between the two professions. We do not support any proposal to modify the market entry test if this has the potential to reduce collaboration between the two professions, since to do so will jeopardise development of patient care and threaten the Pharmacy White Paper aspirations to make better use of pharmacists' skills and expertise.

8. The extension of dispensing of medicines by a doctor to include retail sale of over the counter medicines risks confusing the public, introduces conflicts of interest for the doctor, and deprives the NHS of prescription charge income. Whilst PSNC accepts that in some rural areas where a pharmacy is not viable, a patient may choose to have prescriptions dispensed by their doctor, there is no justification in removing the current contractual term that prevents a doctor from profiting under private arrangements made with his NHS patients. There is no evidence that people in rural areas have difficulty in purchasing OTC medicines; in practice they will ensure they have medicines to hand and purchase them with their other shopping requirements.

9. PSNC regrets that the review of the market entry provisions for dispensing doctors was included in the Pharmacy White Paper. It is right and proper for the NHS to

question whether it obtains best value for money from contracting a simple dispensing service from a doctor but the review and the campaign conducted by dispensing doctors has detracted from the huge benefits that the Pharmacy White Paper proposals could bring to the public in expanding the role of pharmacists to make best use of their expertise.

PNA based market entry test

1. PSNC supports a control of entry test based on a robust PNA.

    a. There is variation in quality as well as content of PNAs at present. In some areas pharmacy contractors have been asked by questionnaire what services they provide, and in some cases what services they would be prepared to provide. This information has been used to develop so called PNAs that do little more than set out what services are already in place and identify services which are not provided (mainly because the PCT has chosen not to commission them).

    b. In some areas a PNA process has been undertaken, but the subsequent document has not been published by the PCT. It is imperative that PNAs are published on the PCT's website.

    c. The control of entry test is an essential component of the contracting arrangements and if this test is to be based upon the PNA there should be a rigorous process of establishing what the patients and public in the area need to meet their healthcare needs at present, and into the foreseeable future, so that pharmacy contractors can better align the services that they provide to these needs.

    <u>PNA Toolkit</u>

    d. PCTs will require support in the development of their PNAs, and a national toolkit setting out the development process and the contents for a PNA should be prepared. PSNC notes that NHS Employers have established a short-term working group to develop tools to support PCTs in their development of PNAs. It will be important that PCTs ensure that the PNA reflects the wider needs assessments undertaken by the PCT and with its partners, in particular PCT and Local Authority produced Joint Strategic Needs Assessments.

    e. Once the toolkit is available, PCTs should work closely with the LPC and the public to develop the PNA. In this way, the PCT can be sure of identifying correctly the services that are available or wanted, that pharmacy contractors could be commissioned to provide.

    <u>Aligning services to PNAs</u>

    f. PSNC, LPCs and existing contractors recognise that where the contractors are not willing or able to provide required services, new applications may be encouraged. A PNA which identifies gaps in service provision should set out clearly those services that the PCT is willing to commission so that LPCs and their pharmacy contractors can negotiate in good faith with the PCT to address those unmet needs. A PNA which identifies services that the PCT is not currently in a position to commission, should indicate when the services might be commissioned, so that LPCs and contractors can prepare to meet those needs at the appropriate time. There should be no unrealistic expectations introduced by publishing a PNA that includes a list of unmet needs that the PCT has no intention of commissioning.

Challenging PNAs

g. The PNA is the foundation on which pharmaceutical services will be commissioned, and it is essential that PCTs are diligent in the development and continuing review of the PNA. Involvement of the public and the LPC will help ensure that a robust PNA is produced, but there should be a mechanism under which members of the public or pharmacy contractors can challenge the PNA, if they are unhappy with the outcome. This process, which may involve scrutiny against the national templates by the Strategic Health Authority for example, will provide greater confidence for pharmacy contractors and the public that the local decisions are appropriate and the services are deliverable. As appeals against PCT control of entry decisions would be against the decision of the PCT in assessing the application against the PNA and not against the PNA itself, an appropriate mechanism to challenge the PNA is necessary as part of this new regime.

h. Some PCTs are undertaking their review of PNAs now, rather than waiting for the guidance that is expected to emerge from the short-term working group convened by NHS Employers. If the PNA is to be the basis of control of entry determinations, it must be robust. PNAs will need to be reviewed regularly, in line with review of the Joint Strategic Needs Assessment.

Removal of the current 'Exemptions'

i. The introduction of a PNA based control of entry test will remove the need for three of the exemptions. As the Control of Entry test is to be modified then it is also appropriate to consider whether the distance selling exemption is required, and if so, whether there is an opportunity to refine the conditions that apply to that exemption.

j. PSNC accepts that the business model of a true distance selling pharmacy would not meet local needs, and hence would fail assessment against the PNA. But, the distance selling exemption is being misused, and PSNC has alerted the Department of Health to a number of cases which demonstrate the misuse. Patients who wish to use mail order or internet to access pharmaceutical services should not be deprived of their choice, but the review of the control of entry regime should include introduction of safeguards to prevent the misuse of the exemption.

k. The guidance prepared by the Department of Health describes these businesses as being 'wholly mail order or internet based (distance-selling) pharmacy services'[1] and that term reflects the rationale for the exemption. The conditions for the exemption should be amended to require that the business is conducted wholly by mail order or by internet (or both) rather than allowing pharmacies to be established which intend simply to operate as a local collection and delivery service, or to operate between closely located premises one of which is a non contract pharmacy.

Piloting the PNA based control of entry test

l. PSNC is very concerned by the impact of the exemption for pharmacies undertaking to provide pharmaceutical services for at least 100 hours per week, and the potential for many more applications to be made pending

[1] The NHS (Pharmaceutical Services) Regulations 2005, Information for Primary Care Trusts, page 76

the introduction of a PNA based test that will remove the need for the current exemptions. Whilst a pilot would ensure that a new PNA test is appropriate, it would delay the commencement of such a test and therefore continue to provide the exemption route to entry to the pharmaceutical list. In these circumstances, PSNC would not wish to see a pilot phase, but would suggest a very early evaluation of a PNA based test, to ensure the objectives of providing PCT with the ability to better manage the location of providers as well as increasing business certainty.

m. If an amendment to primary legislation is needed to give effect to a PNA based test, then the adoption of this new test without a pilot phase introduces risks that problems that develop may take time to resolve, if this requires further modification of primary legislation. We suggest that provision is made to allow problems to be remedied speedily by Regulation.

Decommissioning for poor performance

2. As the new services envisaged in the Pharmacy White Paper are developed, pharmacy contractors will need to ensure that all their services are provided to a high standard and meeting the requirements of customers and patients.

   a. PSNC is working with NHS Employers to agree systems for setting appropriate standards for the Medicines Use Review service, and this includes mechanisms for rewarding positive health outcomes. There are parallels that can be drawn for all the pharmaceutical services, and there is a need to ensure objective standards are established, against which each provider can be assessed.

   b. PSNC agrees that as PCTs are given greater responsibility for the services delivered in their area, there should be tools available to reward high quality as well as addressing substandard performance. These must be introduced concurrently and must be based upon objective standards that are determined nationally (for those pharmaceutical services provided as part of the national framework).

   c. High quality services should be rewarded. Where services are unacceptable, the PCT should provide support to encourage improvement, but we accept that where the support has not led to the achievement of an acceptable standard, sanctions should be available.

   d. In supporting a mechanism for rewarding high quality and addressing poor delivery, PSNC suggests that a system similar to the Quality and Outcomes Framework used in general medical services contracts is adopted for the pharmaceutical services sector. We would be keen to work with the Department and the NHS to develop a suitable framework.

   e. Removal of a contractor's name from the pharmaceutical list is a very serious sanction, but may be needed in some circumstances. The current arrangements either through Fitness to Practise procedures or the NHS Service Committee and Tribunal Regulations are rarely used, but provide the NHS and pharmacy contractors with a fair procedure, with appeal mechanisms. The proposal to introduce a remedial action notice does not add any mechanism that is not already in place – under the agreed Department of Health and PSNC position on addressing shortcomings, a PCT could issue an agreed action plan with an appropriate time for improvements. If improvements are not made during the stated time period, the PCT can pursue the matter using Fitness to Practise or Terms

of Service procedures. We doubt that it would be necessary to supplement current regimes, if the QOF type system is introduced with appropriate levels of reward and withholding.

Time limited contracts

f. PSNC does not agree with the principle of introducing time limited contracts as a means of ensuring quality, because leaving a poorly performing contractor to continue until the end of the contract is indefensible, from a public protection standpoint.

g. Introduction of time limited contracts would not be compatible with the investment a contractor needs to make in taking a lease on premises. Leases will be of varying duration, and although at present a contractor bears the risk that changes in location of general practitioners may affect the income and viability of the pharmacy business, a significantly increased risk of contract termination would need to be reflected by substantial increases in funding.

Appeal mechanism

h. There must be appropriate safeguards to ensure that decisions taken by a PCT relating to a pharmacy contractor's performance can be challenged.

i. Where a difference of opinion arises between the PCT and a contractor, the involvement of the SHA and LPC may provide acceptable informal review mechanisms, but as the seriousness of the consequences increases, an appeal to an independent tribunal will be necessary.

Review of 100 hour exemption

3. Several hundred pharmacies have opened using this exemption from the control of entry test. This has increased costs to the NHS and diluted funding, whilst providing some, but little increase in access to the public. We do not believe there has been any research into the use of the pharmacies in the hours beyond those normally provided by community pharmacies to meet local demand, and we believe such research would show that the cost is disproportionate to the public benefit. The effect in many towns has been to reduce PCTs' ability to plan local service delivery, and the White Paper recognises the benefits of increasing PCTs' ability to have greater powers in future to plan service provision in the light of the PNA.

a. The PNA based control of entry test will remove the need for the exemptions, and will provide the most appropriate mechanism to ensure that the NHS and the public benefits from greater access to pharmaceutical services, whilst increasing business confidence.

b. Attempts to amend the exemption as a temporary measure will introduce uncertainty and impose a burden on business and PCTs as they work to the new procedures. It would be preferable to have no interim measure, but to work quickly to introduce the PNA based control of entry test. In the meantime, there must be a moratorium on new 100 hour applications.

Use of LPS

c. PSNC notes that the Department's revised preference is for the exemption to continue, but for the exempt pharmacies to be commissioned using Local Pharmaceutical Services (LPS) contracts. PSNC does not agree that this is the best alternative to a moratorium pending introduction of the

PNA based test. The apparent support at the listening events may have been based on a lack of awareness of the additional work for business and PCTs, and PCTs may not have the degree of control that they expect.

d. LPS is used currently in only a few cases, other than the Essential Small Pharmacy LPS which replaced the Essential Small Pharmacy Scheme in 2006. Most PCTs therefore have very little, if any, experience in using LPS as a commissioning tool. The development of the skills to commission through LPS within the PCT would impose an additional burden on PCTs. There is also a danger that inappropriate decisions could be taken. There is no appeal right for either applicant or opponent so PCTs and business could face the prospect of increased judicial challenges. This risk will, in our view, be increased by arguments that the neighbourhood served in the hours beyond normal opening hours is different from, and much greater than the neighbourhood that would be defined by reference to times when other pharmacies are open.

e. Before entering into a contract for LPS, the PCT must satisfy the European procurement Directives. The Department of Health guidance indicates that where an application for LPS is made, the PCT must undertake a tendering exercise, even though this may mean awarding the contract to a different party. It would defeat the purpose of the exemption for an applicant to rely on the 100 hour exemption, then be required to participate in a tendering exercise, as a result of which he may not secure the contract. It is understood from informal discussions, that a '100 hours LPS' may need to be a variant of the current LPS arrangements to overcome these problems, but that seems unnecessary if suitable alternatives are available.

f. One reason for LPS appearing to be a preferred option for PCTs and pharmacy contractors may have been because an application under the exemption for a 100 hour pharmacy in a neighbourhood where local pharmaceutical services are being provided would automatically fail to meet the conditions in Regulation 13(1). This means that a PCT has a fairly simple task when determining such an application. Recent decisions by the FHS Appeal Authority suggest that for the exemption not to apply the LPS pharmacy must usually be located in the same neighbourhood in which the 100 hour application is made. The consequences now, would be that clustering could still take place, particularly around the edges of neighbourhood boundaries.

g. In summary we query the compatibility of this route to providing an as of right application process, whilst increasing the ability of PCTs to manage provision of pharmaceutical services. At the listening events, there may not have been a full awareness of some of the concerns such as the obligation to tender and the expertise in commissioning through LPS may not be sufficiently developed. The effect of LPS on the 'exempt' applications is greatly diminished following the recent decisions of the FHS Appeal Authority.

Applicant to justify the 100 hour application

h. If our proposal for early implementation of the PNA based control of entry test is not adopted, then the option that provides increased certainty for business, and greatest power for PCTs to make decisions would be Pharmacy White Paper option 2 – the applicant to justify to the PCT, why the 100 hour application should succeed. The decision making would be similar to (but not as restrictive as) the control of entry test and so PCTs

and business would be relatively comfortable with the concept. An application in a small town, which has no extended hours pharmacy, and which has needs for out of hours pharmaceutical services would be more likely than not to be granted. An application in a small town where there are no extended hours pharmacies but also no identified shortfalls in out of hours provision might be granted or refused depending on the proffered justification, and an application in a small town which is already served by a number of traditional pharmacies and one 100 hour pharmacy would be likely to be rejected unless the applicant offered something more than is currently available. The additional burden would fall where it ought, on the applicant, but he would succeed where the benefits of the 100 hour pharmacy are evident. Primary Care Trusts would regain a degree of control.

i. We recognise that there are some benefits arising from formal contracting between the provider of the service and the PCT. Local Pharmaceutical Services contracts are not the solution, as we say above, but we suggest that a nationally negotiated contract, which can be commissioned locally should be considered. This might also form the basis of the contractual relationship between all pharmacy contractors and PCTs in the future for services beyond the essential service requirements, when the control of entry test is aligned to the Pharmaceutical Needs Assessment. We would welcome the opportunity to discuss the possibilities with the Department in due course.

j. PSNC believes this option gives greater control to PCTs whilst providing improved levels of business certainty.

Minimum level of services

k. The current exemption requires applicants to undertake to provide the Directed services required by the PCT, and we do not see option 4, requiring the applicant to provide particular services as strengthening current provisions. Those areas where the exempt pharmacies do not provide Directed services are where the PCT has decided not to commission any. Requiring a particular range of services will result in PCTs having to commission services whether or not there is identified local need.

l. PSNC has additional concerns, which have existed since the introduction of the exemption in 2005. Where exempt pharmacies are opened and in particular the 100 hour pharmacies, the PCT may decide, if funding is limited, to commission Enhanced services only from the new exempt pharmacy in preference to the traditional existing pharmacies. This results in the existing network of pharmacies suffering the double jeopardy of increased competition from new pharmacies, but also the unavailability of funding for Enhanced services, as the PCT is unwilling or unable to commission these from all the willing providers.

m. PSNC wishes to be assured that if an exempt pharmacy is required to provide a particular service, the funding for that service should also be available to all potential providers, and that the exempt pharmacies are not treated as preferred providers.

Supplementary Lists

4. We think it is appropriate for all pharmacists who provide or assist in providing pharmaceutical services should be subject to the same level of checks and vetting as other NHS healthcare professionals.

    a. The NHS Acts 1977 and 2006 include provision for supplementary lists to be introduced within the NHS, but previous progress towards introducing PCT held lists was deferred in 2006, pending developments in the professional regulation of pharmacists, partly to ensure that there is no duplication. It is now clear that the General Pharmaceutical Council will be established and regulating pharmacists from 2010.

    b. PSNC does not wish to see duplication. If supplementary lists are introduced, for which PCTs are responsible for assessment of suitability, these must not cover the same checking arrangements imposed by the General Pharmaceutical Council. In this stage of development, the government should ensure that section 60 Orders and NHS Regulations provide an adequate degree of vetting, but should not lead to duplication.

    c. The pharmacy workforce has a greater proportion of peripatetic workers than some other health professions. This means that a pharmacist may be more likely to work across multiple PCT boundaries than other healthcare professionals. The burden for PCTs in carrying out duplicate checks, and for pharmacists in continually applying to new PCTs must be avoided.

    d. Duplication could be avoided if pharmacists were entitled to apply for inclusion in just one central list. It would be possible for the list to be hosted by the General Pharmaceutical Council or the NHS Business Services Authority. The benefit of a list prepared and maintained by the General Pharmaceutical Council would be to introduce recognition across the home countries.

    e. As many pharmacists work near to or across national borders the lists if prepared by primary care organisations should be recognised across the borders. The fitness to practise regimes are identical in the NHS (England) Act 2006 and the NHS (Wales) Act 2006 having both originated from the NHS Act 1977, and there is no justification for imposing barriers to free movement of pharmacists across these borders. Although the legislative regime in Scotland is not so closely aligned to that of England and Wales, there would seem to be benefit also in ensuring that pharmacists working across the English - Scottish (or Welsh – Scottish) borders should also be able to rely on mutual recognition of any rights to assist in providing pharmaceutical services.

    f. The NHS should therefore work with the devolved administrations to develop a combined list which covers all of the home countries, so that pharmacists can move across these boundaries as well as the boundaries of the Primary Care Organisations with a minimum of formality.

    g. Pharmacists have applied to PCT smartcard registration authorities and have been subject to robust identity checks. It seems unnecessary to duplicate these checks when preparing supplementary lists.

    h. We recognise that the performers' lists arrangements involve assessment of a person's fitness to practise, and PCTs currently undertake those checks. If this is the model to be followed, then we suggest that because

of the mobility of the pharmacist workforce, a Home PCT type arrangement is introduced based upon either the pharmacist's regular place of work (if they are based in one place) or the pharmacist's home address if the pharmacist is likely to work across several PCT areas. The PCTs, after carrying out their assessment could feed the data into the national list, so that it can be accessed by other PCTs and by pharmacy contractors undertaking pre-employment checks.

i. The Safeguarding Vulnerable Groups Act 2006 introduces an additional tier of vetting. The NHS could reduce the massive workload involved by vetting all registered healthcare professionals as part of maintaining performers' and providers' lists. This would ensure that no healthcare professional would be able to work within the NHS without being vetted under these arrangements – this would be needed to ensure that self employed registered healthcare professionals are subjected to the same Independent Safeguarding Authority (ISA) vetting procedure. As the Safeguarding Vulnerable Groups Act comes into force in October 2009, PSNC is keen to see the framework for supplementary lists (or an equivalent) introduced in a timely manner, so that there is no duplication of vetting under the Safeguarding Vulnerable Groups Act with later checking under supplementary lists legislation.

Technicians

j. At present, technicians working in a pharmacy contractor's business are not required to be registered and they are required to work under the supervision of a pharmacist. The pharmacist is therefore responsible for the conduct of the technician. In these circumstances we do not believe it is necessary for technicians to be subject to a requirement for ISA vetting or inclusion in a supplementary list.

Dispensing doctors – market entry

General position on access to services

5. Collaboration between all primary care practitioners will provide the best care for patients.

   a. The White Paper sets out a new vision for pharmacy, using the skills of pharmacists to further enhance patient care and develop better use of the skills available in primary care.

   b. PSNC accepts that in a rural area where a pharmacy is not viable, a patient should be able to have their prescriptions dispensed by their doctor.

   c. Pharmacy is moving from a dispensing only service, to one in which the skills and expertise of the pharmacist are incorporated into primary health care provision. The services provided by pharmacists derive from their expertise in the use of medicines. As the role and contribution of pharmacists grows beyond the simple supply of medicines, the care of patients who do not have access to a pharmacist in a pharmacy will become progressively unequal.

   d. For example, patients who are able to access a pharmacy can receive a Medicines Use Review from a pharmacist, whose expertise in the use of medicines is unmatched throughout primary care. Patients without access to a pharmacy may receive only a Dispensing Review of Use of Medicines

(DRUM) carried out by dispensary staff in a dispensing doctor's practice. As the British Medical Association guidance says, 'it is not the same as the MUR in community pharmacy and does not cover all aspects of that advanced service for community pharmacists'. PSNC has recently piloted an investigation into customer responses to consulting rooms; the responses suggest that patients welcome the improvements to facilities brought about by installing confidential consultation areas and they are already being used for a wider range of consultations. As patients become more accustomed to these facilities and the services being provided by their pharmacist in their pharmacy, the services envisaged in the White Paper become a reality for those patients able to access a pharmacy.

e. Chapter 4 of the consultation begins with the generally accepted precept that doctors prescribe medicines and pharmacists dispense them. It goes on to say that good practice requires, wherever possible, the separation of the prescribing and supply functions. We support this principle. The proposed NHS service specification[2] for Pharmacist Independent Prescribers also supports separation of prescribing and dispensing except in exceptional circumstances. The service specification also recommends that a second suitably competent person must be involved in checking the accuracy of the medicines provided, and wherever possible, carrying out a clinical check. The current policy evidenced by this service specification supports the continuation of the principle that wherever possible there should be separation of prescribing and dispensing. Taken together with more recent policy decisions on patient safety (such as the implementation of the Shipman Inquiry recommendations and revised arrangements for the Responsible Pharmacist) means that the best service is provided where patients are able to access dispensing services from a pharmacy.

f. All the new services which develop, including those in the White Paper which call on the skills and expertise of pharmacists, can be provided only in a pharmacy. Where there is a pharmacy nearby, patients of the dispensing doctor should be able to receive the pharmacist services from the pharmacy. This is already the case with support for self care and signposting services, which pharmacies will provide to anybody asking for help in the pharmacy.

Option 4

g. Option 4, would allow a dispensing doctor to dispense if there was only one pharmacy within 1.5km of the surgery, and the doctor would be entitled to dispense for all his patients. This option would have a catastrophic effect on the availability of pharmacy services in rural areas.

h. In some rural areas a pharmacy is not viable. In many rural areas, pharmacy services are provided where the service is just viable, and the level of business is such as to support only one pharmacy. In these circumstances the reduced pharmacy income caused by allowing the dispensing doctor to dispense for all his patients would force closure of the pharmacy.

[2] The NHS service specification for prescribing by Pharmacist Independent Prescribers has been agreed between PSNC and the Department of Health, and is due to be published shortly.

Option 1

i. For the above reasons we do not agree that it is appropriate at this time to modify the market entry provisions for dispensing doctors, and support option 1 – no change.

Common regulatory route

j. In time the revised control of entry provisions linked to the PCT's PNA will affect the distribution of and services provided by pharmacies. It is important that those provisions do not have the effect of creating a barrier to entry to pharmacy that does not apply to dispensing doctors, since that would have the effect of reducing the availability of a comprehensive range of pharmaceutical services provided by a pharmacist in a pharmacy, and replacing it with a simple dispensing only service provided from a doctors' practice.

k. It is therefore appropriate for the market entry provisions for doctors in rural areas to be aligned to those applying in pharmacy at that time. The public would benefit more from the availability of a comprehensive range of pharmaceutical services provided by a pharmacist in a pharmacy as compared with a simple dispensing only service, but in circumstances where a pharmacy is not viable, a dispensing service may be needed.

l. The PNA based control of entry test will apply to the address of pharmacy premises, and therefore the common regulatory test should equally apply to dispensing doctor premises in rural areas. If applications are made in respect of branch surgeries, then the patients to whom the doctor is permitted to dispense should be only those registered at and routinely using that branch surgery. There have been instances where dispensing doctors have secured dispensing rights in branch surgeries but have provided dispensed medicines from the main surgery located close to a pharmacy, where they would not have been able to secure premises approval. This loophole must be closed by requiring any dispensing to take place only in approved premises and for the patient to collect their medicines only from approved premises, not from premises that would not satisfy the reformed common regulatory test.

Serious difficulty

m. We note that the White Paper records that 99% of the population – even those living in the most deprived areas – can get to a pharmacy within 20 minutes by car and 96% by walking or using public transport[3]. Most pharmacies provide a collection service where prescriptions are collected by the pharmacy from the medical practice and are dispensed to await collection by the patient. Many pharmacies also provide a free delivery service to the home of some or all of their patients, particularly for those patients who have difficulty visiting the pharmacy.

n. The White Paper also proposes that where a delivery service is not available, a PCT may commission one[4].

o. It is therefore highly unlikely that any patients would satisfy the 'serious difficulty' test, and eligibility for dispensing based on serious difficulty is

[3] Pharmacy in England: Building on Strengths – delivering the future, paragraph 1.9
[4] ibid paragraph 8.73

therefore not needed. The serious difficulty test often appears arbitrary and is not the subject of an appeal mechanism.

p. If despite these comments, serious difficulty is to be continued, PSNC would wish the criteria to be set out in regulations, and to exclude cases where a local pharmacy would undertake to provide a delivery service to the patient.

<u>Availability of pharmacy services to dispensing doctor patients</u>

q. In our work with NHS Employers we expect to develop pharmacy services in which dispensing is merely a part of a patient focussed service.

r. This comprehensive pharmacy service should be available to all patients who can access it readily from a pharmacy and that would include dispensing doctor patients. Collaboration between all GPs including those that dispense, and pharmacists providing the pharmacy services should be encouraged, to ensure that all appropriate information necessary for patient care is shared.

<u>Summary of PSNC position on services in rural areas</u>

s. The dispensing service provided by dispensing doctors is necessary where a pharmacy would not be viable. The new pharmacy services to be developed which utilise the skills and expertise of pharmacists cannot be provided by dispensing doctors and it is essential to recognise that dispensing practices will be unable to provide the new services.

OTC medicine sale from dispensing doctor practices

6. PSNC recognises that in rural areas where a pharmacy is unviable, patients may choose to have medicines dispensed by a doctor. No evidence has been produced that patients in these areas have difficulty in obtaining OTC medicines. In practice we believe they will purchase medicines when shopping for food and other needs and will ensure they have stocks available for when they are needed.

a. A dispensing doctor may currently sell OTC medicines, by setting up a company separate from his primary medical services contract and trade with planning permission from premises which he funds and for which he provides appropriate members of staff.

b. Patients in a rural area who are exempt from paying the NHS prescription charge will not wish to visit their dispensing doctor's practice and then be advised to purchase an over the counter remedy. They will want to continue to receive their medicine free of charge, on prescription.

c. A patient who is liable to pay prescription charges may decide that they wish to purchase a medicine over the counter if the cost is less than the prescription charge. A dispensing doctor may calculate that in some circumstances his profit will be greater from dispensing than from selling the OTC medicine and on other occasions, his profit may be greater if he sells the OTC medicine. This creates a commercial conflict of interest for dispensing doctors, which could act to the detriment of patients.

d. PSNC believes that permitting dispensing doctors to sell OTC medicines will cause confusion, since patients accessing their NHS general practitioner will be accustomed to receiving only NHS services rather than a mix of NHS and private services. A patient purchasing an OTC medicine

from their dispensing doctor would not for example, appreciate that the transaction is one that is being carried out privately, and therefore complaints could not be dealt with through NHS procedures.

e. The sale of medicines in pharmacy is being reviewed, and regulations have recently been laid in which a responsible pharmacist will be required to set down procedures, and monitor these on a daily basis to ensure the systems are safe. There will be increased record keeping, and the responsible pharmacist will be required to be on the premises for the substantial majority of the day, to monitor procedures etc. There is also to be a review of the supervision requirements, and some activities will be delegated only to trained and registered staff. It would be wrong for the public protection aspects of the medicines legislation to be strengthened in pharmacies, but then for OTC medicines to be sold by unregistered staff in a dispensing doctor practice.

f. For all the above reasons, PSNC strongly opposes the amendment of the NHS regulations to permit the sale of OTC medicines by dispensing doctors to their NHS patients.

Other matters

7. Local Involvement Networks

PSNC is content with proposals to update the NHS (Pharmaceutical Services) Regulations 2005 to refer to the Local Involvement Networks.

8. Independent Optometrist Prescribers

PSNC is content with proposals to include Independent Optometrist Prescribers in the list of persons whose prescriptions can be dispensed under the NHS (Pharmaceutical Services) Regulations 2005 or NHS (Local Pharmaceutical Services etc.) Regulations 2006.

9. Withdrawal from the Pharmaceutical List

PSNC is content with proposals to amend the NHS (Pharmaceutical Services) Regulations 2005 to permit the PCT to retain a pharmacy contractor 'on the pharmaceutical list' if he is facing fitness to practise proceedings, provided that any change of ownership application is allowed to proceed.

10. Necessary or Desirable test

There was considerable debate at the time the NHS Bill was passing through parliament about the change to the control of entry test, and assurances were given by the minister that the changed wording of the NHS Act 2006 as a consolidating Act does not affect the interpretation of the control of entry test. On this understanding, PSNC is content with proposals to update the NHS (Pharmaceutical Services) Regulations 2005 to refer to the 'necessary or expedient' test.

11. Changes of hours for 100 hour pharmacies

a. PSNC is content with proposals to amend the NHS (Pharmaceutical Services) Regulations 2005 to allow a 100 hour pharmacy to apply to change the days and or times at which the pharmacy is obliged to provide pharmaceutical services, providing that amended hours continue to meet the minimum of 100 hours required for granting the original application for inclusion in the pharmaceutical list.

b. The regulations should provide power for the PCT to accept, accept in part or reject such an application, in the same way that the PCT can treat applications from 'traditional' pharmacies.

c. It is not clear whether all pharmacies providing in excess of 100 hours per week have indicated to the PCT which hours are their 'contractual' hours and those which exceed 100 and are thus non contractual. The first step in providing for notification of change of non contractual hours is for the PCT to be sure which hours are non-contractual and those which are contractual. This should be achieved by requiring the pharmacy contractor to notify the PCT within six months of the amendment to the Regulations of which of his hours of opening constitute his contractual 100 hours, and which of his hours of opening are his non-contractual hours. This notification will parallel the notification that traditional pharmacies had to undertake in 2005, where there was an unidentified mix of contractual and non-contractual hours.

d. PSNC does not accept that there should be charges introduced for the processing of change of hours applications. In many cases, the need to change hours has been caused by changes to medical services provided by nearby surgeries, and if a charge was payable, this may prove to be a disincentive to aligning hours of opening to address local needs.

12. Inducements

a. PSNC welcomes the proposal to amend the NHS (Pharmaceutical Services) Regulations 2005 to keep pace with developments in pharmacy practice, by excluding products which are supplied to encourage and promote better health from the prohibition on inducements.

b. PSNC has expressed concern to the Department of Health on a number of occasions about direction of prescriptions by a prescriber to a particular pharmacy. This concern is heightened where the prescriber has a commercial interest in the pharmacy or where the pharmacy and prescriber enter into commercial arrangements which reward the prescriber in recognition of the number of prescriptions presented. PSNC therefore welcomes the proposals to amend the prohibition on inducements. However, it is unclear from the summary in the consultation whether the proposal will go far enough. On one interpretation of the consultation it appears that a recommendation to use a particular pharmacy by a prescriber who has an interest in the pharmacy may be permitted if the patient is first made aware of the commercial interest. If that is what is intended, that would be objectionable, as it extends the potential for the prescriber to exert undue influence.

13. Local Pharmaceutical Services – PCT as Provider

a. PSNC strongly opposes the proposal that a PCT should be permitted to be an LPS provider. The proposal seems to be at odds with NHS commissioning policy published by the Department over the last few years that expects PCTs to focus their attention on being a commissioner of services rather than being a provider of services.

b. Under the NHS Act 2006 a PCT cannot provide pharmaceutical services or Local Pharmaceutical Services itself. Whilst this differs from the arrangements that exist for medical services, where the PCT is itself able to provide those services, PSNC believes that the pharmacy model differs markedly from that applying to medical services.

c. It is indeed necessary in some circumstances for a PCT to be able to provide medical services where it is unable to attract a provider. However, pharmacy as an independent healthcare provider is a highly competitive business, and in the absence of evidence PSNC cannot envisage any circumstances where a PCT will be unable to secure agreement from a pharmacy to provide pharmaceutical services or Local Pharmaceutical Services.

d. Under the current arrangements, pharmacy owners apply for inclusion in the pharmaceutical list, and the PCT has an obligation to consider those applications under the terms set out in the NHS Act. If the PCT was itself authorised to provide Local Pharmaceutical Services, it could turn down such an application and instead provide the services through a Local Pharmaceutical Services contract with itself. That, PSNC believes, would introduce a conflict of interest that is not capable of being remedied.

e. There may be circumstances in the case of a national emergency, where the infrastructure breaks down, where such powers may be necessary. PSNC is willing to discuss whether appropriate provisions could be included in the Pandemic legislation.

14. Local Pharmaceutical Services – withdrawal from an LPS scheme prior to signing an agreement

PSNC is content with the proposal that a PCT should be able to withdraw from an LPS Scheme before the agreement is signed.