

APPLICATIONS TO PROVIDE NHS PHARMACEUTICAL SERVICES REVIEW OF CONTROL OF ENTRY ARRANGEMENTS

CONSULTATION RESPONSE FROM NHS LANARKSHIRE

Thank you for the opportunity to comment on your proposals. Set out below is the philosophy which we have applied to our detailed response and provides background as to why in some cases our response goes beyond the question being posed.

PLANNED CARE

Granting an NHS Pharmaceutical contract has recurrent resource implications for NHS Boards. It commits money which cannot then be used for other services. Where the Board considers that the application meets the statutory test the resource allocation can be justified in terms of service priorities but otherwise the granting of a contract represents waste. We believe that a properly developed Pharmacy Care Services Plan (PCSP) which is publicly available and has been the subject of proper research and consultation is an essential tool to good decision making and that Pharmacy Practice Committee (PPC) and National Appeal Panel (NAP) decision making should be driven by that plan. We therefore fully support change that will give greater status to PCSPs and therefore move us in this direction.

APPEALS

Unlike most appellate systems the current appeals process is essentially a retrial. We believe that the appeals process should be about addressing unfair decision making by the PPC and **not** about giving the applicant a second chance to improve upon the arguments he has deployed before the PPC or to introduce new ones which the PPC has not heard.

The national figures are compelling and show that approaching 60% of all applications are now appealed. We believe that this cannot be explained by flawed decision making by the PPCs alone. It must be driven by a growing belief on the part of applicants that it is the NAP rather than the PPC which makes the decision on their application and that the PPC is only an inconvenient but obligatory stage in the process. If this perception is to be reversed then at the very least NAP must make it clear that on matters of judgement its function is not to substitute its own judgement for that of the PPC where it finds that the judgement that the PPC has made falls within a range of views open to a reasonable man. The defining of "Neighbourhood" provides a good example. We believe that it is NAP's responsibility to decide on whether the PPC has reached its decision by applying the judicial guidance in a reasoned and reasonable way. Only if it concludes that the PPC has not should it go on to define the neighbourhood differently.

We support proposals that help clarify the NAP's role as correcting unfair decision making by the PPC rather than rehearing the application afresh.

FAIRNESS, BALANCE AND COST

Checks and balances and transparency of decision making are important elements in achieving fairness but they also come at a cost and here too a balance needs to be struck. We believe that some of the proposed changes alter the existing balance unfavourably and in other cases would represent improvement only if accompanied by other change not yet proposed. We also believe that some of the costs attached to running the current system cannot be justified as being in the public interest by the value they add to the quality of decision making.

With these introductory comments as context we now provide our responses to the specific consultation questions.

Volume of applications/ repeat applications (paras 32-40)

37. Views are invited on these issues/ proposals. Do you believe that an NHS Board should be able to consider applications at a first stage and decide whether or not a full PPC is required or whether they can decide that current provision is adequate?

We agree with the concept of a preliminary hearing to assess whether or not an application should be rejected or be heard at a full Pharmacy Practices Committee (PPC).

The procedures and practices for such a hearing must be robust and effective to avoid this being simply another stage in the overall process which would prolong matters. Thus the process must have the capacity to reject applications which are not suitable for a full hearing and also have the capacity to speedily agree to a full hearing without prejudicing the outcome of a full hearing.

Procedurally, we propose that the Chair of the PPC reviews the application to decide if a full or a preliminary hearing is required. If the Chair decides upon a preliminary hearing (s)he would hear the applicant's case face to face. The PPC Chair is supported by access to the NHS Boards Pharmaceutical Care Services Plan and the applicant has to make a prima facie case as to why their application is necessary or desirable to secure an adequate pharmaceutical service. The outcome – either a rejection or a move to a full PPC hearing - would be communicated in writing to the applicant giving reasons for the decision.

As stated in the consultation an appeals process would be required. Appeals at this stage would only be by an applicant who disagrees with a judgement that a

full PPC hearing is not required. Appeals could be made to the National Appeal Panel(NAP).

38. Whether or not a first stage is introduced, Scottish Government proposes to introduce an amendment which would allow NHS Boards to consider applications and/ or appeals which have already been rejected in a specified time period as a relevant factor when considering the question of adequate provision. Do you agree with this proposal?

39. Do you agree that 12 months is an acceptable length of time (since a previous application was rejected/ failed at appeal) prior to which an applicant would be asked to establish that a significant change in the area/ neighbourhood had occurred?

We wish to respond to Questions 38 & 39 together

It is important that we do not give a specific time period too much prominence in the decision making. It is not time, per se, which is the issue. Rather it is a material change of circumstance which is important e.g. in terms of

- Contemporary standards of service provision
- Changes in access or access standards
- Patient population volume or demographics

As a general rule, in order to avoid a rejection at a preliminary hearing, an application for a contract in a premises which has previously been rejected (or one close enough to that address that there could be no dispute that it would be reasonable for the PPC Chair holding a preliminary hearing to base their judgement on the neighbourhood previously defined by the PPC) must indicate that there has been a material change in the requirements for services within the neighbourhood.

One of the prime purposes of this suggestion is to minimise frequent reapplications for the same premises. In many ways the arguments expressed in the paragraph above are true regardless of the time frame between applications. Yet, we realise that neighbourhoods and their needs can and do change over time. Given that these are best assessed by a full PPC, we propose that further applications to the same premises be accepted for a full hearing if 2 years or more have elapsed since the last rejection decision by either the PPC or NAP, but the preliminary hearing concept can be applied for an earlier application.

40. Scottish Government proposes an amendment to require Boards to consider their Pharmaceutical Care Services Plans as part of their consideration as to the adequacy of current NHS pharmaceutical services in an area. Do you agree with this proposal?

We strongly agree with this proposal because we believe that a properly developed PCSP which is publicly available and has been the subject of proper research and consultation is an essential tool to good decision making and that PPC and NAP decision making should be driven by that plan. We therefore fully support change that will give greater status to PCSPs and therefore move us in this direction.

However, there are currently some practical issues which should, and could, be addressed before implementation. The main issue is that PCSPs vary greatly throughout the country. Further guidance from SGHD about the requirements of PCSPs would be valuable to implement best practice.

It would also only seem fair that if PCSPs were to be used in this way that they be published by each HB.

Relocations (paras 41-45)

43. The Scottish Government proposes to alter the Regulations such that they refer to “no significant affect” and thus allowing room for Health Boards to consider this freedom in more circumstances. Do you agree with this proposal?

We would need a clear definition of significant effect.

The Oxford popular dictionary definition of appreciable is: perceptible, considerable

and of significant is: important

There are nuances between these open to different interpretations. What is important to one person may be different to that of another

We need to get back to the main purpose of this legislation which was to provide a degree of stability and confidence for contractors so they feel confident about investing in their business. If this remains the purpose then a legislative framework to achieve that end should be established.

Is the reality not that save situations e.g. compulsory purchase orders, contractors would not voluntarily seek a minor relocation unless it was going to be cost effective for them in terms of business growth? Thus their anticipated growth in business would need to outstrip the expense of a relocation (over a period of time) and hence there would almost always be an appreciable or important effect.

Therefore a policy decision needs to be made regarding the concept of a minor relocation. We would propose that minor relocations should be allowed and

supported if they develop services in a manner which addresses a gap in the PCSP for that locality. In this way, minor relocations for the purpose of improved service provision (which is likely to have an appreciable or important effect on the applicant and other contractors within the neighbourhood) can be supported, but only if it is necessary to address an identified service deficiency

45. Scottish Government proposes to alter the Regulations such that where a minor relocation is approved, the existing entry on the pharmaceutical list will be amended, rather than result in a new entry. Do you agree with this proposal?

Yes. We also believe that the same concept be introduced for relocations other than minor so there can be no loophole which would allow the original pharmacy to retain an NHS Pharmacy contract.

Notice of a pharmacy application (paras 46-49)

47. The Scottish Government proposes to alter the Regulations to:-

a) ensure that dispensing GPs are informed of an application in the locality where they operate,

It seems fair and reasonable that dispensing GPs be informed - not least because a PPC would want to have all views and evidence before it when considering its decision.

The key though is not about merely informing dispensing GPs. Nowadays they would pick it up from the public consultation anyway – and should do via the AMAC – albeit is a matter for the AMAC themselves as to how they do their business. A more important decision could be whether or not dispensing GPs get offered the status of official interested parties and the subsequent rights to participate at oral hearings.

We support dispensing GPs being given the status of interested parties. The dispensing GPs would clearly have local knowledge and albeit there may be temptations to submit information which is extraneous to the statutory test, this should not deflect a PPC from maintaining its focus.

b) ensure that CHPs are informed of applications.

We oppose this proposal as far as it relates to individual applications.

CHPs are committees of the Health Board and part of the managed service but the regulations are such that it is the PPC that makes the decision. It would be complex and potentially interfere with the independence (and value) of the PPC concept if the CHP as part of the Health Board provides an opinion to a PPC – constituted primarily from lay members to make a decision on behalf of the NHS Board - about whether or not a particular application be granted?

To avoid this complexity there is a value reviewing whether the decision making for any particular application is delegated to a PPC or made directly within the Health Board in accordance with its Pharmaceutical Care Services Plan?

As previously stated our philosophy throughout this response is to promote the value of a thoroughly researched, consulted upon and published PCSP. CHPs would certainly have a significant influence on developing the PCSP.

49. The Scottish Government will continue to consider [public consultation arrangements] and whether any other changes are necessary in the future. Your comments are welcomed on the issue of public consultation. (Para 48 refers)

The arrangements for public consultation have only recently been introduced by Boards and different Boards carry out this exercise in different ways.

It is already clear that the exercise, (perhaps regardless of precise methodology) promotes a mixed response rate and strength of feeling from those parties consulted, not only in terms of volume of responses e.g. from nil to overwhelming when perhaps there is a long established dispensing GP practice located within the proposed neighborhood, but also frustration over, or ignorance of the precise decision making processes around the statutory test to be applied by the Pharmacy Practices Committee.

Boards will therefore require to monitor the efficacy of their methods of consultation, and the merits of having a clear and concise nationally agreed patient information leaflet compiled detailing the procedures which could be advertised during the consultation process should be explored (paying due regard to have them available in different formats/languages). This could be valuable in directing respondents to the key decision making factors, which in turn would help respondents provide their opinions in a manner most likely to influence the decision making.

Systems such as newspaper advertising are useful for informing the public but may fall short of the requirements for true public consultation. Exploration of the potential and practicalities of applying the standards described in CEL 4 (2010) Informing, Engaging and Consulting people in Developing Health and Community care services would be valuable

We suspect that in depth public consultation would be best suited to developing the Health Board PCSP which would then act as the standard for decision making for all applications.

Membership of PPCs (paras 50-54)

53. The Scottish Government therefore intends to remove the need for PPC nominations to be sought from specified bodies/ contractor groups. Rather, we intend to alter the Regulations such that a pool of PPC nominations is populated by Boards. Do you agree with this proposal?

The most important thing is that that all members of the PPC have the skills to carry out the task in a fair minded and open manner. Systems for recruitment and training are therefore important. Local experience suggests that the initial training is useful but it may be valuable to supplement that with the opportunity to witness a real hearing as an observer before taking up the position of an active member. With PCSPs gaining in importance it would be important that PPC members are given training in the philosophy underpinning the Health Boards PCSP.

It is also important that the PPC have ready access to a range of expertise relating to procedural issues and the practicalities of providing an NHS pharmaceutical contract service.

We believe that the membership of PPCs could be streamlined. Pharmacy contractor representation is essential but one such representative per PPC hearing would suffice.

We would also propose that PPCs are constituted to have 4 voting members - 2 lay members, 1 x RPSGB representative and the Chair. In the event of a tie the Chair would have the casting vote. The Regulations would need to clearly define the membership, voting rights and quorum.

We believe that this constitution would work well and it would be administratively easier to arrange meetings.

We note that the current regulations make no comment on the timeframe within which PPCs must be convened, and we propose that such a time frame (6 months) be adopted within the regulations.

54. Likewise, a question was raised as to the necessity of the specific provision which requires that lay members must not be (or have been) health professionals. Indeed, it has been suggested that representation of another health profession could offer a helpful and complementary view of the decision being made. Comments are sought on this issue.

We do not believe that healthcare professionals should be excluded.

Like the suggested response to Q53, the important issue is that the PPC members have the skills and attitude to carry out the task in a fair and open minded manner. Listening carefully to the evidence presented, debating that with colleagues, articulating their own opinions and ultimately making a rational decision are the key skills.

Potential members whether they have a health care professional background or not, should join a PPC without any prejudice

The statutory test – ‘necessary or desirable’ and related PPC processes (paras 55-56)

56. The Scottish Government will consider what guidance can be provided in light of responses to this consultation. We will also continue to explore those other related issues including training needs for PPC members and discuss this with Boards in due course. Comments are welcome.

Training courses such as the recent one in Edinburgh are valuable. Local training for new members is essential and discussed previously in Q 53. Once more we reiterate that training in the philosophy underpinning the Health Board’s PCSP is a key issue.

Appeals Process – the National Appeals Panel (NAP) (paras 57-65)

59. The Scottish Government proposes to strengthen the appeal process such that it can divert more applications back to the Board and, for example, request that they remedy any procedural issues. Do you agree with this proposal?

Yes, we strongly agree.

Local panels have local knowledge and that is beneficial. If the appeal is on a procedural issue then presumably this referral back to the local panel will detail the initial procedural problem and should help avoid any recurrence. One of the frustrations of the current system is the lack of feedback about why the NAP agree to hear an appeal

Our introductory comments at the beginning of this letter make further suggestions about the appeal procedure and are repeated below.

Unlike most appellate systems our current appeals process is essentially a retrial. We believe that the appeals process should be about addressing unfair

decision making by the PPC and **not** about giving the applicant a second chance to improve upon the arguments he has deployed before the PPC or to introduce new ones which the PPC has not heard.

The national figures are compelling and show that approaching 60% of all applications are now appealed. We believe that this cannot be explained by flawed decision making by the PPCs alone. It must be driven by a growing belief on the part of applicants that it is the NAP rather than the PPC which makes the decision on their application and that the PPC is only an inconvenient but obligatory stage in the process. If this perception is to be reversed then at the very least NAP must make it clear that on matters of judgement its function is not to substitute its own judgement for that of the PPC where it finds that the judgement that the PPC has made falls within a range of views open to a reasonable man. The defining of "Neighbourhood" provides a good example. We believe that it is NAP's responsibility to decide on whether the PPC has reached its decision by applying the judicial guidance in a reasoned and reasonable way. Only if it concludes that the PPC has not should it go on to define the neighbourhood differently.

We support proposals that help clarify the NAP's role as correcting unfair decision making by the PPC rather than rehearing the application afresh.

62. The Scottish Government proposes a change to the Regulations which would result in only the applicant themselves having a right to appeal the decision of the Health Board/ PPC in relation to their own application. Do you agree with this proposal?

No this seems unfair. There is a history of appeals by applicants and interested parties being successful and unsuccessful.

If there were a procedural irregularity leading to a decision against an interested party, or, if there was a frank case of bad decision making against an interested party, then it would be unjust that there be no right of appeal.

65. The Scottish Government proposes an amendment requiring the NAP to hear representation from affected Boards at NAP hearings. Do you agree with this proposal?

We believe that PPCs have local knowledge and come to their decisions after hearing and weighing up all of the evidence. With a change in regulation and a greater status for Health Board PCSPs the decisions will become more objective and reasoned in delivering services aligned to carefully researched and agreed local need. This is to be welcomed.

We therefore agree that the NAP should respect this local process and seek representation from PPCs at any appeal hearings.

Membership of the National Appeal Panel (NAP) (paras 66-69)

68. The Scottish Government proposes to alter the composition of the NAP. We are minded to do this with a view to reducing the number of members and with a view to removing the need to seek nominations from individual organisations. Likewise, we are keen to explore the potential of the membership including wider representation, although the consideration will need to remain in relation to NHS pharmaceutical services. We would be keen to hear views on these proposals.

We reiterate our answers to Questions 53 & 54.

Like the suggested response to Q53, the important issue is that the NAP members have the skills and attitude to carry out the task in a fair and open minded manner. Listening carefully to the evidence presented, debating that with colleagues, articulating their own opinions and ultimately making a rational decision are the key skills. NAP members would also need to know and understand the philosophy of the PCSP for the Health Board the application was for.

Potential members, whether they have a health care professional background or not, should join a NAP without any prejudice.

NAPs need to be supported with expertise especially that relating to procedural issues and the practicalities of providing an NHS pharmaceutical contract service.

George Lindsay
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On behalf of NHS Lanarkshire Board
18th May 2010