**Draft regulations under the Health Act 2009: Market entry by means of pharmaceutical needs assessments and quality and performance.**

**Royal Pharmaceutical Society Response**

The Royal Pharmaceutical Society (RPS) is the new professional body for every pharmacist in Great Britain. We are the only body that represents all sectors of pharmacy in Great Britain.

The RPS leads and supports the development of the pharmacy profession within the context of the public benefit. This includes the advancement of science, practice, education and knowledge in pharmacy. In addition, it promotes the profession's policies and views to a range of external stakeholders in a number of different forums.

Its functions and services include:

**Leadership, representation and advocacy**: promoting the status of the pharmacy profession and ensuring that pharmacy's voice is heard by governments, the media and the public.

**Professional development, education and support**: helping pharmacists to advance their careers through professional advancement, career advice and guidance on good practice.

**Professional networking and publications**: creating a series of communication channels to enable pharmacists to discuss areas of common interest.

**General comments**

The RPS supports the principle that pharmaceutical needs assessments (PNA) should be used as a market entry, and where necessary, exit tool. We believe that the appropriate use of PNAs could result in better managed and planned pharmaceutical services for patients and the public. However, we have a number of concerns around the implementation of this in practice and these are outlined below:

- With the ongoing restructure of the NHS much of the expertise around the development of PNAs at a local level is being lost as many pharmaceutical advisers posts have been shed by Primary Care Trusts (PCTS)
- Subject to Parliamentary approval, Health and Wellbeing Boards will be responsible for undertaking PNAs and there is no guarantee that they will have the skills and expertise required to do this in a robust manner. It is likely to be the local arrangements of the NHS Commissioning Board (local field forces) who will make the decision regarding the granting of NHS contracts for pharmacies. This will mean that the agency responsible for developing and maintaining the decision making framework will be split from the body responsible for making the decision.
- Health and wellbeing boards must have access to pharmaceutical advice and in depth knowledge of community pharmacy when they undertake the development and maintenance of PNAs.
- Currently, the content and value of PNAs is variable as is the process that is undertaken to produce the PNA which could result in variability of pharmaceutical services and access to these in different localities. This could also lead to an increase in appeals.

Regarding the current and future exemptions, we would encourage the government to consider a moratorium on the granting of new pharmacy applications under the current exemptions. We do not agree with the proposed exception to carry forward the distance-selling pharmacy exemption.

Performance and quality procedures are to be introduced to assure the quality of pharmaceutical services provided by pharmacies and dispensing appliance contractors. Before a contractor is suspended or removed from a pharmaceutical list the involvement of the National Clinical Assessment Service (NCAS) should be sought, as it currently is for doctors and dentists. This would ensure a fair and facilitated national approach. We also believe that equivalent performance and quality provisions should be introduced for dispensing doctors to assure the quality of the pharmaceutical services they provide.

**Questions:**

1. **Do you agree the draft regulations enable market entry to be based on identification of current and future needs?**

We do agree.

2. **Are there any other matters which you feel need to be included in or omitted from the draft regulations which deal with applications based on current or future needs?**

Yes.

The PNAs that have been prepared and published in 2011 were not developed with market entry provisions in mind so are unlikely to be fit for purpose. As previously mentioned, the content, usefulness and quality of PNAs is variable and a study by the Pharmaceutical Services Negotiating Committee (PSNC) has highlighted this variability with only 12% of Local Pharmaceutical Committees (LPCs) scoring the quality of PNAs as a 5 (a 5 being the highest quality).

Some PCTs may have identified the need for a service, but due to the current financial climate or other reasons, have not commissioned the required service to meet this need. They may have hoped that current service providers would provide the service at no charge. However, this would not be a sustainable option as the continuity of such a service could not be guaranteed.

Under these market entry regulations, the PCT would be in a position where they may have no option but to grant applications to meet the need identified by the PNA. We would suggest that if the PCT is not in a position to commission a service at present, then the applications ought to be determined as if it was a future need application and be deferred until a time where the commissioning of the service is possible.

In many areas there are changes to pharmaceutical service provision throughout the lifetime of a PNA with new pharmacies opening, relocations or new services being provided as, for example, new homes are built which impact on the local neighbourhood. Supplementary statements to the PNAs should be produced when such changes occur and this requirement will become even more significant when PNAs are used to assess current need applications.

It is unclear how contracts can be awarded in a robust manner without standardisation of the content of PNAs. There also needs to be more clarity on who will be responsible for ensuring the quality and content of the PNA once PCTs have gone.

**3. Do you agree the draft regulations that enable market entry in respect of applications offering to meet identified 'current or future improvements' or 'better access to pharmaceutical services'?**

We do agree but we would like to raise one concern.

We are concerned that the ability of PCTs to 'hold' applications may stifle innovation. If a contractor does considerable groundwork on a new contract application and submits this only to be told it is 'on hold' other contractors may well apply and usurp the original applicant. If others can take advantage of his groundwork and eventually win a contract, why should any, other than organisations with contingency funds to cover losses, apply to support future communities and medical services?

**4. Are there any other matter which you feel need to be included or omitted from the draft regulations which deal with applications for 'current or future improvements' or 'better access to pharmaceutical services'?**

No.

**5. Do you agree the draft regulations that enable market entry in respect of applications offering 'unforseen benefits'?**

Yes.

**6. Are there any other matters which you feel need to be included in or omitted from draft regulations dealing with 'unforseen benefits'?**

No.

**7. Do the draft regulations provide a solution to the current difficulties dispensing appliance contractors (DACs) are facing in applying for entry to a PCTs pharmaceutical list? If not, what alternative solution would you propose?**

We have no specific comments on this question.

**8. Do they provide an appropriate balance between enabling an improvement in the provision of appliances to patients whilst ensuring the NHS does not incur additional costs for little or no perceived benefit?**

We have no specific comments on this question.

**9. Do you agree with all the proposed exceptions to the new market entry test listed in paragraph 1 of Chapter 5? If not, please tell us which types of application should be excepted from the new market entry test and the reasons why.**

No

We agree with all of the proposed excepted applications other than the distance-selling pharmacies and our reasons for this are given in our response to Q10.

**10. Do you agree that distance-selling application should not be subject to the new market entry test? If not, please give reasons for your answer.**

No, we do not agree

We do not believe there is any evidence of unmet need for ecommerce and market forces should prevail. Distance selling pharmacy contracts do have an effect (unintentional) on the balance of local pharmaceutical services that undermines the concept of PNA driven market entry.

The NHS Information Centre has published details[1] of the number of distance-selling pharmacy applications granted since 2005. The number granted in the year 2010 to 2011 (60) represents an increase of 330 per cent over the number granted in the first year of the exemption. In contrast, the 100 hour exemption has increased by 260 per cent since the first year. Since the exemption was introduced, the number of applications granted under this exemption has increased year on year. None of the other exemptions have increased year on year. We use this statistic in support of our view that the exemption is growing in its popularity, as the inadequacy of the conditions for its use become known.

The proposed market entry test based on PNAs is intended to alter the dynamics of pharmacy applications. Under the current processes, it is solely the applicant that decides where a pharmacy is to be located. Parliament's intention when the Health Act 2009 introduced the pharmaceutical needs based principles, was to shift to the NHS, the control of where pharmacies would locate in future, by setting out needs in the PCT's PNA. Providing an exception for distance-selling pharmacies, would have to be done in such a way as to ensure that it does not undermine the NHS' ability to plan the location of pharmacies.

The current regulations have been interpreted by some as prohibiting the provision of services 'in the vicinity of' the distance selling pharmacy, but a stronger provision is needed. The e-commerce exemption was introduced to provide patients with a choice of being able to obtain their medicines through a delivery service, because this may be more convenient, or because they prefer the relative 'anonymity' of a mail order or internet business. It was never intended that the patient would visit a non-pharmacy retail premises, and receive their pharmaceutical services through a 'back door'.

There is no evidence that the public find a lack of opportunity to receive pharmaceutical services through e-commerce routes. NHS choices[2] currently list 134 internet pharmacies. This provides much greater level of choice than would exist in a normal neighbourhood where there may be just two or three pharmacies from which a patient is able to make a choice. In the absence of evidence that the public have an insufficient choice of e-commerce providers, the exception should be removed from the regulations.

In addition to the true e-commerce pharmacies, many pharmacies currently provide a delivery service, and therefore we do not believe that there is a need to provide an exception to the market entry test to provide patients with the adequate provision of services through delivery services. As with dispensing appliance contractors, the PNA based test is not appropriate for determining whether an e-commerce type application should be granted.

We suggest that if evidence emerges after the regulations come into force, that the public is being deprived of a reasonable choice of e-commerce businesses, then a similar proposal to that made above in respect of dispensing appliance contractors could be considered - that is the National

[1] http://www.ic.nhs.uk/pubs/pharmser0111
[2] http://www.nhs.uk/servicedirectories/Pages/InternetPharmaciesAtoZ.aspx

Health Service Commissioning Board could consider applications on a national level where it is satisfied that the business is being set up to provide pharmaceutical services through e-commerce rather than as an application benefiting from the weaknesses that have become evident over the last six years.

We hope that the Department gives our proposal to remove the exemption due consideration, and that Ministers decide not to press ahead with the exception unless evidence emerges of detriment to the public and NHS.

We are also aware that such pharmacies can offer advanced and enhanced services, provided these are not provided at the dispensing location. We feel that a national e-commerce pharmacy is unlikely to provide Enhanced services of relevance to a local PCT. In the current regulations there is the uneasy tension between allowing distance selling pharmacies to provide Enhanced services if they are commissioned by their PCT or the neighbouring PCT, but the pharmacy cannot be directed to provide Enhanced services through the provisions of Regulation 13(3). A distance-selling pharmacy that operates as an e-commerce pharmacy is likely to see patients from the four corners of the country, and would be able to provide Enhanced services only for those commissioned by its PCT or a neighbouring PCT. Of the Enhanced services specified in the Directions, we can think of none that should be mandated from an e-commerce pharmacy, because of the wide geographical catchment area that would be expected. In the circumstances we question whether the e-commerce pharmacies should provide any Enhanced services at all, since these are by their nature, services that are locally delivered.

**11. Under the current 2005 regulations, an application for one of the four exemptions is refused if the neighbourhood in which the premises will be located is designated for LPS. Do you consider PCTs should continue to have the safeguard of being able to refuse distance-selling premises applications in an area where there is a LPS designation? If yes, please give reasons.**

Yes.

It is interesting that the designation of an area for the purposes of developing local pharmaceutical services is needed to be given consideration. If a distance-selling pharmacy was truly an e-commerce business, then it would have little impact on the local pharmaceutical services being developed by the PCT. The need to consider LPS designations in this way supports our argument that some distance-selling pharmacies are not e-commerce businesses but are actually local service providers.

The RPS accepts that distance-selling pharmacies that are established in an area where the PCT is attempting to establish a local pharmaceutical services contract, could undermine the planning that goes into such developments, and therefore agrees that the LPS designation should continue to allow the PCT to defer applications whilst the designation continues (a designation would normally lapse within a year of being made).

But, to replicate the current regulations, the proposed regulations would need to go further and provide a power not only for the PCT to defer any application where there is an LPS designation, but also a mandatory provision similar to the current regulation 13(1) requiring the PCT to refuse the distance-selling pharmacy application if there are local pharmaceutical services provided in the area where the premises named in the application are to be located.

**12. Will the introduction of a 'no significant change relocation' make relocating or administering relocations of a pharmacy premises within a PCT's area easier than the current 'minor relocations' provisions? If not, please give reasons**

We believe that the current minor relocation provisions are well understood by pharmacists and commissioners and if the provisions are changed to those of a 'no significant change relocation' there will need to be period of time to understand the changes and differences. We do not think the new provisions will necessarily make the determination of applications easier.

**13. Are the conditions relating to 'no significant change' applications clear? Do you have any comments about the new 'no significant change' or 'detriment' test?**

We agree that the conditions are clear.

**14. Do you consider the notifications and appeals procedures in the draft regulations adequate?**

The conditions are that the only appeal against a PNA is via a judicial review. Since contractors will depend on a robust PNA for fair and appropriate decisions regarding contracts, how can contract decision be made if the PNA is not current? We have already cited our concerns that PNAs are already out of date and that the quality of their content is variable. In defending existing pharmacy contracts, how can contractors be expected to challenge the PNA when a contract is awarded on the basis of outdated information?

**15. Do you consider the notification and appeal procedures in draft schedules 2 and 3 are clear?**

We do agree that they are clear.

**16. Are the draft regulations sufficiently clear about how and under what criteria PCTs can initiate measures to deal with performance matters for chemist contractors?**

We agree that the criteria regarding performance matters are very clear but the impact assessment makes a number of statements that would require clarification. In regards to performance issues, breach notices, withdrawal of funding and ultimately removal of contracts, we are concerned to read that it is assumed that 420 pharmacies will receive a breach notice, 140 have funding withheld and 72 have their contract removed when there is no mention of the mechanism for policing quality standards or what will be expected from pharmacy contractors. Once PCTs have been abolished, there is no clarity as to who will be responsible for performance matters and how will they ensure this does not overrule or duplicate the work of the GPhC. Rather than be a punitive system, any drive to improve standards should support improvement. To that end, we would recommend that NCAS is involved before any measures are introduced to ensure a nationally fair and equitable system.

The process of appeal also needs to be made clear. There is also ambiguity regarding fines with mention of fines being proportional to the contractor, not to the individual contract and this needs to be further clarified.

**17. Are these proportionate and reasonable? If not, what changes would you suggest and why?**

Please see our answer to Q16 above.

**18. The intention of the Advisory Group has been to transfer the 2005 regulations and amendments agreed by the Group since relating to rural dispensing without any significant**

**change, but taking the opportunity to make the regulations clearer and make some agreed minor modifications. Do you agree with what has been done? If not, please tell us why not.**

No , we do not completely agree

We are concerned that the quality and performance provisions will not apply to medical practitioners providing pharmaceutical services. We believe it is wrong to apply one set of standards to pharmacy dispensing practice and another to doctor dispensing practice. To do so leads to inequality and denies the public the same service just because they happen to live in a rural area.

We do not see why, if dispensing doctors are providing pharmaceutical services under the same regulations as pharmacies and dispensing appliance contractors, they should not be subject to identical quality and performance measures. To maintain different quality and performance measures is an inconsistent approach and could lead to variation in monitoring, support and enforcement.

**19. Does the information which accompanies the regulations including the draft guidance adequately clarify the requirements and procedures set out in the regulations?**

Yes it does

**20. If Ministers were to proceed following consultation, do you have a view on whether the regulations should be implemented by PCTs or the NHS Commissioning Board, subject to Parliamentary approval?'**

We would suggest that they are implemented by PCTs. However, we repeat our request that until the PNA based market entry test is introduced that there should be a moratorium on the granting of applications under the current exemptions.

The RPS believes there are three benefits in PCTs implementing the new market entry test:

- The new test would be introduced without unnecessary delay;
- The new test would be applied against the PNAs which were developed by the PCTs, so there will be familiarity with PNA; and
- In the course of amending the regulations to take account of the NHS reforms introduced in the Health and Social Care Bill (subject to parliamentary process), any lessons learned during the introduction can be accommodated

**21. Do you want to make any other comments outside of the above questions?**

We are concerned that some service delivery involves work moving from hospital to primary care and as this is currently quite fluid, it is unlikely to be captured within the PNA. For example, community pharmacies are now providing oral chemotherapy medicines and advice in the community, whereas this provision only used to only occur in secondary care.

**22. Do you have any comments on the draft impact assessment?**

Yes

The impact assessment[3] suggests that the total number of new entrants applying under the exemptions would continue at the current rate of 150 per year for two years, declining to 20 per

[3] Paragraph 49

year by year 10. We dispute this assumption. The number of exempt applications granted in the last year for which figures are available was 498, and the number of outstanding applications made in the final quarter of 2010 to 2011 was 490. We anticipate that just before the regulations come into force, there will be a substantial number of applications made. This number will in our view exceed the forecast 150 by a substantial margin. We do not understand how there will be 20 exempt applications per year by year 10, since the exemptions (other than distance-selling pharmacies) are due to be removed from the regulations.

Similarly, we do not agree with the assumption that there will be an increase of 50 distance-selling pharmacies per year for the first two years, declining to 20 per year by year 10. There were 60 applications granted under the distance selling exemption, in the year 2010 – 2011, which as we have stated above, has shown a year on year increase. From our survey of LPCs, if we scale up the responses to all areas, there could be as many as 70 pending applications in December 2011. Once it becomes the only exception from the PNA based test for new pharmacies, we expect the number to rise even further.

The net reduction of pharmacies and the calculation of savings from lower entry will not be achieved. We again suggest that the NHS and patients do not benefit from greater choice of e-commerce businesses.

The Impact assessment also includes[4] an estimate of 72 pharmacies being de-listed under the performance elements. We find this estimate alarming, because it has been stated that de-listing is a last resort. Whilst we cannot provide an estimate ourselves, we believe that by including this estimate in the impact assessment, it may provide tacit encouragement to PCTs to use this sanction in circumstances where lesser sanctions are more appropriate.

**23. Are there matters not included in the draft Equity Impact Analysis which should be?**

No

Lindsey Gilpin
Chair, English Pharmacy Board

*For further information or any queries you may have on our consultation response please contact Heidi Wright at heidi.wright@rpharms.com or 0207 572 2602.*

[4] Paragraph 54