Your Name: Jocelyn Parkes
Organisation (if applicable): Royal Pharmaceutical Society
Email address: Jocelyn.parkes@rpharms.com
Telephone number: 02920730310
Your address: 2 Ash Tree Court, Woodsy Close< Cardiff Gate Business Park, Cardiff , Cf23 8RW

How to respond
Please submit your comments by 27 April 2012, in any of the following ways:
Email: Pharmaceuticalservicesconsultation@wales.gsi.gov.uk
Post: Pharmaceutical Services Regulations Consultation
Welsh Government
Department of Public Health and Health Professionals
Health & Social Services Directorate General
Cathays Park, Cardiff, CF10 3NQ

Additional Information
Email: Pharmaceuticalservicesconsultation@wales.gsi.gov.uk

Response from: The Royal Pharmaceutical Society

The Royal Pharmaceutical Society (RPS) welcomes the opportunity to contribute its views on; Proposals to reform and modernise the NHS (Pharmaceutical Services) Regulations 1992

The RPS is the professional body for pharmacists in Wales and across Great Britain. We are the only body that represents all sectors of pharmacy.

The RPS promotes and protects the health and well-being of the public through the professional leadership and development of the pharmacy profession. 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.

General comments

The RPS is pleased and supportive that the Welsh Government is undertaking a review of the 1992 Regulations, but we are concerned that this does not go far enough to address current Governmental and professional policy intent and could be a missed opportunity to further advance the provision of pharmaceutical care and services in Wales. There is little mention in the consultation document about how the proposed changes will address some of the major issues in pharmaceutical care at the moment. The document describes no vision or roadmap for pharmacy to which the Government in intending pharmacy to move toward.

The RPS Vision for pharmacists is as the recognised professional member of the healthcare team responsible for choosing pharmacotherapy, universally accessible on the frontline to provide pharmaceutical care and entrusted by the patient to take care of

their every pharmaceutical need. Consolidation of the regulations is a useful exercise, however, more innovative changes will be needed if this vision is to be realised. Pharmacists as prescribers, fully integrated into healthcare pathways and as part of the multidisciplinary team are all consistent with the vision of the Welsh Government as laid out in Together for Health, but will require much more fundamental change to the framework pharmacy currently operates in. There is little in the consultation that outlines how the proposed changes will move Wales towards this vision.

The number of pharmacy contracts in Wales has been relatively static for the last decade. There have been very few new entrants, with the only shift being in the mix of ownership of pharmacies, namely from independent to more multiple owned. At the same time, the number of dispensed items has increased dramatically and newer enhanced services have been introduced. The level of workload now needs to be considered and any changes to the regulations need to be mindful of today workload capacity and ultimately expected workload capacity if the policy intent of Welsh Government is to be delivered in the future .

Additionally whilst the current legal framework has created a stable network of pharmacy and prevented movement and clustering around NHS prescription issuing sites, it is an overly complicated system that has the potential to stifle innovation and have influence on raising standards within existing pharmacies. We would suggest a robust system is introduced that allows for the Government commitment that "citizens across Wales should have access to the full range of NHS pharmaceutical services" and a degree of pragmatism is introduced where patients are not receiving the full range of pharmaceutical services.

We would suggest that if the Welsh Government are thinking of making changes to the regulations they use this opportunity to align there thinking with the report from the Health and Social Care committee inquiry into the pharmacy contract ,when available, and examine all models of service provision by pharmacists . It is imperative that the two exercises happen in harmony and ultimately the time may now be right for a root and branch review of how pharmaceutical care in Wales is delivered.

Consultation Questions

Respondents are asked to mark the appropriate boxes to indicate their response.
It is proposed that the Regulations, in their current form, are revoked and replaced with the NHS Pharmaceutical Services Regulations 2012 ("the new Regulations").
The new Regulations would:

- Consolidate amendments made to the Regulation over many years.
- Ensure consistent use of language, definitions and interpretations.
- Set out the tests relating to control of entry for inclusion in a pharmaceutical list and from doctors, in rural areas, wishing to provide pharmaceutical services in a more logical and structured way which can be more easily followed and understood.
- Separate out the detailed provisions governing the making of applications to provide pharmaceutical services from the procedures to be followed by LHBs in respect of determining those applications in order to improve clarity.

Question 1: Do you agree with this proposal?

The question above has 4 proposals and we propose to address these separately.

Additionally the first question in the consultation is asking about the proposal to consolidate the Regulations rather than reviewing them. The two are separate and differing processes and if the Regulations are reviewed they may no longer need consolidating.

The process of consolidation is to bring together the activities into a single piece of legislation. We believe this should not be done in isolation from review and amendment of the Regulations but the Welsh Assembly should make it clear which process they are intending to undertake.

Consolidate amendments made to the Regulation over many years

Yes - A set of consolidated regulations as a framework to work within is a very desirable concept for the pharmacy profession, Local Health Boards and the public. However Regulations as a legal framework are often difficult to interpret in a non legal environment so must be supported with guidance documents and explanatory notes.

Additionally this consultation is going beyond consolidating the Regulations, it is also proposing changes to the regulations and the two issues should be taken separately. In that we agree with the consultation exercise but some of the previously laid regulations should now be reviewed and not consolidated on mass until outstanding issues have been addressed.

The regulations that are put in place relating to “Control of Entry” need to reflect existing and developing service provision under the community pharmacy contract but also be flexible enough to ensure that they can encompass future service modernisation and integration in Wales that fits with developing policy. Recent government policy, such as Together for Health, calls for radical service redesign, greater integration of services and a shift in focus from service provision in secondary care. There is little in the consultation that outlines how the proposed changes will enable these to happen.

Ensure consistent use of language, definitions and interpretations

Yes - The regulations that are put in place relating to “Control of Entry” need to reflect existing and developing service provision under the community pharmacy contract but also be flexible enough to ensure that they can encompass future service modernisation in Wales.

The need to ensure consistent language, definitions and interpretation is vital to understanding and working with the Regulations, and as part of consolidation exercise should be done to reflect the changes over the past 2 decades.

However this is an opportunity to review and consult on the Regulations and as such the definitions and interpretations of them must be reviewed.

It is with the development of services in mind that we suggest that the definition of pharmaceutical services needs to be clarified and updated.

Previously pharmaceutical services related to the supply of prescribed drugs and appliances. This is now out dated and a more encompassing definition is needed to reflect both the essential and advanced services in the new pharmacy contract and the potential developments for service delivery that enhanced services offer.

An assessment of adequacy of existing pharmaceutical service provision should then be made within the context of the broader new definition. This assessment needs to take a patient centred approach to medicines management; health promotion and access to medication needs but also needs to appraise “pharmaceutical services” within the wider provision of health and social care service delivery. This is applicable to the primary care setting, intermediate care and the interface between care settings. Additionally there should be clarity and review around all of the definitions in respect to the encompassing services development and the prospect of future proofing the Regulations. Terms such as necessary, desirable, expedient, prejudice and neighbourhood which have a significant impact on the granting of contracts should be clearly defined, or in the absence of a clear definition not used.

Set out the tests relating to control of entry for inclusion in a pharmaceutical list and from doctors, in rural areas, wishing to provide pharmaceutical services in a more logical and structured way which can be more easily followed and understood.

We are supportive of the principle of a structured process or “set of tests” to the control of entry, for inclusion in a pharmaceutical list and from doctors, in a rural area.

However the control of entry process must be mindful of service development into the next decade and beyond and to ensure that: any “set of tests” that are introduced must have a process for review of effectiveness and refinement built into the development of these tests.

Additionally any such assessment and application process should be consistent across Wales whilst allowing reflection of local needs and encouraging innovation of service. Procedures should be open, transparent, subject to scrutiny and followed in a consistent manner across the Local Health Boards. The tests must be robust enough to remove any local bias and thus reduce the need for subsequent appeal.

Any such tests should be a balance between the need to provide a degree of stability to those providing services within an area, and the need to encourage innovation. There should also be the ability to test existing service provision if it is failing to meet required standards or levels of service.

The need for pharmaceutical services in rural areas provided by Doctors is a separate issue. In addressing the provision of dispensing services through Dispensing Doctor practices we support the Welsh Government view that pharmacy is the preferred option for the provision of dispensing services. The RPS believes that all members of the Welsh public should have access to the expertise of a pharmacist and the pharmaceutical care services they provide. This review may be an opportunity for the

Welsh Government to review existing provision in rural areas to ensure as many patients as possible are having pharmaceutical services delivered through a pharmacy. One such mechanism to ensure this can happen is to support development of the 'Essential Small Pharmacy Scheme'.

On the extremely rare occasions when it is not possible to secure patient access to pharmacy services, in the interests of patient safety the provision of services to patients in rural areas needs to comply with the same standards as those provided in other settings, and any "set of tests" must reflect this stance. For example, the General Pharmaceutical Council is currently consulting on the standards needed for pharmacy premises. Once agreed, those same standards should apply to all premises supplying medicines to the public.

Separate out the detailed provisions governing the making of applications to provide pharmaceutical services from the procedures to be followed by LHBs in respect of determining those applications in order to improve clarity.

It is proposed that the new Regulations provide for an application to provide pharmaceutical services to be dismissed where it is made within a fixed period after a determination that there is adequate provision of pharmaceutical services in the same neighbourhood to which the application relates and where the applicant has provided no evidence of significant change since the previous determination was made.

Question 2: **Do you agree with this proposal?**
Yes
No **X**
No view

The main benefits of such a policy would seem to be a reduction in bureaucracy for those involved in processing applications and a degree of stability to existing contractors. These are sensible reasons, but it is difficult to see a benefit to patients in the 'closing of lists', and there are risks that it could stifle innovation, particularly in a system that is based on pharmaceutical need as it is intended. Pharmaceutical need might not just depend on the population, but the innovative services a new entrant proposed to provide.

Question 3: Do you consider a maximum fixed period of 3 years after a determination to be the appropriate length of time before which the LHB must determine subsequent applications?
Yes
No (please explain) **X**
No view

We are concerned that the ability of HB to put an area on 'hold' may stifle innovation (as described above), and may lead to a curious situation after the defined timescale when a large number of similar applications are proposed.

Question 4: What factors do you consider need to be taken into account when

determining whether or not significant changes have occurred in the neighbourhood?

It is proposed that it would help to levy a fee for all applications for inclusion in or amendment to a pharmaceutical list. This would deter speculative bids and help defray NHS costs. Applicants would pay on a graduated scale with a lower fee payable for applications for a minor relocation, and a higher fee payable for a full application. The fee would be non-refundable whether the application was successful or not.

Question 5: Do you agree with this proposal?

Yes
No **X**
No View

We would support a fee that covered the administration costs required to process it. The process and set of tests should be robust enough to avoid speculative applications. If needed, a triage process could be used.

It is proposed that the maximum amount of time be reduced for:

(i) the period for which a grant of preliminary consent is effective (i.e. the time within which an applicant granted preliminary consent must make a full application to be included in a pharmaceutical list), which is currently 12 months but can be extended for such further period as the LHB considers reasonable in the circumstances; and

(ii) the time within which the provision of services must be commenced following grant of an application for inclusion in or amendment to a pharmaceutical list, which is currently up to 24 months from the grant of the application.

Question 6: Do you agree that the maximum periods should be reduced?
Yes
No
No View **X**

If an application based on pharmaceutical needs has been deemed appropriate in the interest of patient safety and services the application should proceed in a timely manner.

Question 7: Are the following maximum periods reasonable: 6 months for the period for which a grant of preliminary consent is effective; and 6 months for the commencement of services following the grant of a full application?
Yes
No
No View **X**

The application process should take place within a clear designated timeframe, with allowances for exceptional circumstances should they arise. This should apply to all stages in the process, from initial application to the opening of the pharmacy.

It is proposed that for an application to relocate pharmacy premises to be considered a “minor relocation” the LHB must be satisfied that essentially the same population will be served by the provision of pharmaceutical services at the new premises as are served by the current premises; rather than being satisfied that the relocation is within the same neighbourhood.

Question 8: Do you agree with the proposal that, for a relocation to be considered “minor”, the requirement be that essentially the same population will be served rather than the current requirement that the relocation must be within the neighbourhood?
Yes
No
No View **X**

We would ask for clarity on if the definition of neighbourhood was being replaced or reviewed in this consolidation process. Any relocation should also be judged against the assessment of pharmaceutical need being met by that pharmacy.

Question 9: How might an applicant be able to demonstrate that “essentially the same population would be served” before and subsequent to the relocation?
Yes
No
No View **X**

Question 10: Do you consider there to be any merit in simplifying the minor relocation process further, for example that all relocations under a specified distance are automatically granted or where the relocation would result in a GP surgery and pharmacy being co-located?
Yes
No
No View **X**

Question 11: Do you consider that there would need to be safeguards against pharmacies undertaking a series of minor relocations over a short period time?
Yes **X**
No
No View

Any safeguards would be based on the assessment of pharmaceutical need against which that pharmacy was providing services.

Question 12: Do you consider that it would be sufficient to require that a pharmacy provided pharmaceutical services from a location, to which they relocated, for a minimum period of 12 months before they could apply for a further relocation?
Yes
No
No View **X**

One of the aims of this consolidation exercise is to simplify the process for relocation and we would question if the introducing of rigid controls would achieve this for the applicants.

It is proposed that regulations should allow minor relocations across LHB boundaries.

Question 13: Do you agree with proposals to allow minor relocations across LHB boundaries?
Yes **X**
No
No View

Within the lifespan of the current 1992 Regulations there have been several changes to Health Boards boundaries and as such these are poor criteria for inclusion in the minor relocations process.

It is proposed that regulations should provide for the temporary relocation of a pharmacy in specified circumstances (for example in an emergency).

Question 14: Do you agree with proposals that a LHB be able to allow the temporary relocation of a pharmacy (for a maximum of 6 months) in specified circumstances (for example in an emergency)?
Yes **X**
No
No View

Provision of continuous pharmaceutical care during an emergency situation is paramount and provisions should be made to accommodate this.

It is proposed that the Welsh Government provides guidance to LHBs on the determination of neighbourhoods, and that that guidance advises LHBs to have due consideration to geographic areas about which demographic information is collated (e.g. Super Output Areas) when defining the boundaries of neighbourhoods.

Question 15: What issues, if any, do you foresee in moving to a system where neighbourhoods, as defined for the purpose of determining applications, are coterminous with individual, or groups of, Super Output Areas?
Yes
No
No View **X**

We would ask for clarity on the issue of Super Output Areas , especially in terms of their robustness in defining what is a suitable area for an application. The definition of a population that needs pharmaceutical care and service provision should not be based on a desk top activity which super output areas appear to be.

It is proposed that applications by doctors to provide pharmaceutical services should be determined using the same criteria as those used to determine applications by pharmacists.

Question 16: Do you agree with this proposal?
Yes **X**
No
No View

In addressing the provision of dispensing services through dispensing doctor practices we support the Welsh Government view that the provision of dispensing services should be through pharmacy. In the exceptional cases where they may be a need for considering alternative means of delivering dispensing services, a range of alternative model of service delivery should be considered. This could include hub and spoke dispensing, or dispensing doctor services. However any such alternative models should not compromise the need to supply the full range of pharmaceutical care to patients. If this is not delivered as part of the supply service then provision should be made through advanced services to plan for gaps in service provision through domiciliary MUR and DMR services.

This not- with-standing, in the interest of patient safety, the provision of services to patients in rural areas needs to comply with the same standards as those provided in other settings. Equal standards for training and qualification for support staff must also apply. The delivery of high standards of healthcare to the public must be of prime consideration.

The GMS and community pharmacy contract mean that the current decision process for the provision of pharmaceutical services is now outdated and whilst this review of control of entry process considers some aspects there are still outstanding issues that need to be addressed. Changes to GMS contact since the introduction of the Regulations have effectively meant that GPs are fully funded for providing GMS services. Thus dispensing services are no longer a consideration in the prejudice of GMS services.

We ask that the Welsh Government reviews the current Regulations relating to dispensing in rural areas to update the process and allow for a new wider definition of pharmaceutical services and a full pharmaceutical needs assessment. Within this revised process there should be an option to reconsider existing provision, taking into account changes in patient need, service advancement and changes in demographics. Within this review there would need to be an agreement on the definition of dispensing services provided by GPs under the Act and the wider definition of services provided through pharmacy. Essential Small Pharmacy Scheme services could also be considered within this new framework. Paramount in any such review should be the right of the public in Wales to benefit from and have access to pharmacists, a pharmacy and the full range of services they provide.

It is proposed that applicants to the pharmaceutical list have to provide certain information about their fitness to practise.

Question 17: Do you agree with this proposal?

Yes

No **X**
No View

The RPS supports the management and handling of risk based regulation, and would ask for clarity that any proposed changes to the Regulations are undertaken in a sensible and proportionate way.

We have a number of concerns in relation to the maintenance of 'performers' lists, in particular the issue around duplication. The General Pharmaceutical Council maintains a list of registered Pharmacists and Technicians and operate fitness to practise processes, they have powers to suspend pharmacist and registered technicians if deemed appropriate, and additional they plan to introduce premise standards. We would ask for clarity as to why these additionally measures of providing *certain information about fitness to practise* will offer any greater public safeguards than are already in place. We have concerns about the unnecessary duplication of information and processes and would support one register and one repository of fitness to practise information, with a concordat on information sharing.

Pharmaceutical lists and database are introducing another level of bureaucracy within the LHB and one of the aims of this consolidation is to simplify the process.

The Pharmaceutical list is currently the list of contractors providing services within the Health Boards locality. We would ask for clarity if the Welsh Government is introducing Fitness to Practise performance list for these contractors which would be different to the locums and pharmacist providing the pharmaceutical service. Additionally 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.. 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.

Question 18: Do you consider that either alone, or in combination, the proposals outlined in the consultation will have any impact on the number or type of appeals received by Welsh Ministers?

Yes
No
No View **X**

It is proposed that, in the future, applications to be included in the pharmaceutical list should be determined on the basis of the contribution that the proposed services might make to address local needs assessed by LHBs. This could require a change in the

way the Regulations define pharmaceutical services and would require that LHBs undertook specific local pharmaceutical needs assessments.

Question 19: Do you agree with this proposal?
Yes **x**
No
No View

In principal we are supportive of the idea of local services being planned and deliver on the basis of locally assessed need.

The regulations that are put in place relating to “Control of Entry” need to reflect existing and developing service provision under the community pharmacy contract but also be flexible enough to ensure that they can encompass future service modernisation in Wales.

It is with this development of services in mind that we suggest that the definition of *pharmaceutical services* needs to be clarified and updated.

Previously *pharmaceutical services* related to the supply of prescribed drugs and appliances. This is now out dated and a more encompassing definition is needed to reflect both the essential and advanced services in the new pharmacy contract and the potential developments for service delivery that enhanced services will offer in future. An assessment of adequacy of pharmaceutical service provision needs to be made within the context of the broader new definition. This assessment needs to take an integrated and patient centred approach to the medicines management, health promotion and access to medication needs but also needs to appraise “pharmaceutical services” within the wider provision of health and social care service delivery. This is applicable to the primary care setting, intermediate care and the interface between care settings.

Question 20: We have asked a number of specific questions. If you have any related issues which we have not specifically addressed, please use this space to report them:

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:

- There is no expertise at present around the development of PNAs at a local level, and there would need to be shared learning in developing the skills and expertise required to do this in a robust, consistent manner across the Welsh health Boards
- The experience from colleagues in England has been that currently, the content and value of PNAs is variable as is the process that is undertaken to produce the PNA which results in variability of pharmaceutical services and access to these in different localities leading to an increase in appeals. There seems to be little

evidence of a change in service provision to reflect local need or a greater integration of pharmacy services into wider care pathways.

- All forms of pharmacy should be considered in the PNA application including the introduction of vending machines and introduction of collection supporting pharmacies not in the immediate locality.
- 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.
- To ensure consistency and hence reduce the number of appeals we would recommend that PNA are taken forward on an all Wales basis, with the use of an all Wales template, amended for local interpretation. Additionally where expertise exists in interpreting and using needs assessment this should be accessible across Wales.
- The provision of pharmaceutical needs may also depend on the willingness and ability of pharmacies to provide it. The number of pharmacies has not increased by any huge amount while the number of prescription items and services has. Skill mixes within pharmacies have adapted to deal with this but it may also be that different models of service provision by pharmacists could be examined as well.
- The Vision from Welsh Government is that “citizens across Wales should have access to the full range of NHS pharmaceutical services". They have demonstrated their commitment to this through policy and strategy development that incorporate pharmacy as a key delivery method in primary care. Consolidation of the regulations is a useful exercise, however, more innovative changes will be needed if this vision is to be realised. Pharmacists as prescribers, fully integrated into healthcare pathways and as part of the multidisciplinary team are all consistent with the vision of the Welsh Government as laid out in Together for health, but will require a more fundamental change to the framework pharmacy currently operates in.