## Consultation Response Form

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Q1: Do you agree that all services provided under sections 80 and 81 of the NHS Wales Act should be included in the definition of pharmaceutical services for the purposes of the Regulations?

Yes. It is important that Pharmaceutical Needs Assessments (PNAs) should incorporate the core pharmaceutical services as outlined in Section 80 of the 2006 Wales Act and additional pharmaceutical services as outlined in Section 81. This will ensure that the broadest range of services can be developed and delivered to patients via community pharmacy. This will also support the appropriate shift of services from hospital to the community and contribute to the future development and expansion of primary care services in Wales.

Q2: Do you agree that the health board should be placed under an obligation to consider all pharmaceutical services and are there any other persons providing those services that should be considered?

Yes. To ensure a robust process, it is important that all pharmaceutical services are considered. A thorough review of services will adequately allow for the identification of both population needs and service gaps to contribute to effective forward planning in each Health Board area.

Q3: Do you believe there is anything that could be added to the list of required information to improve the content of a pharmaceutical needs assessment?

We are content with the list of required information as set out in Schedule 1 of the 2020 regulations.

Q4: Is five years an appropriate interval between pharmaceutical needs assessments?

Yes. Five years would be an appropriate interval between the formal development of PNAs, however we believe flexibility should be built in to allow for important changes to be made in the interim period. Greater flexibility would allow Health Boards to be agile enough to respond proactively to gaps in provision arising over time. We believe such flexibility would have a positive impact on patient care, allowing for greater responsiveness to population need.

Q5: Do you agree the health board should be under a duty to revise its pharmaceutical needs assessment once it considers there are significant changes to the circumstances in its area; for example when a large housing development takes place?

Yes. We would like to see the 2020 regulations enable significant agility among Health Boards to respond to changes in circumstances to meet population need. However, as previously stated above, flexibility is needed between formal the formal development of PNAs to empower Health Boards to undertake necessary revisions and to make appropriate changes without the need for a full PNA being issued.

We would recommend a mechanism within the regulations to allow for such flexibility to ensure Health Boards can be responsive without the need for an onerous process to be followed. We believe that streaming the process will also reduce any uncertainty among affected contractors and limit the impact on patient care. Essentiality it is important that patient care is not adversely impacted upon by the introduction of the 2020 regulations, the requirement for PNA's and ongoing revisions to take account of unforeseen changes.

Q6: Do you agree with the list of persons who must be consulted on the contents of an assessment?

We are supportive of the list of persons who must be consulted.

\*Please note that Local Pharmaceutical Committee's no longer exit in Wales and we would advise deleting these from the list.

Q7: Are there any other persons who should be consulted?

We would also recommended that Regional Partnership Bodies should also be added to the list to ensure health and social care bodies can adequately work together to respond to the population assessment carried out in accordance with Section 14 of the Partnership Arrangements (Wales) Regulations 2015.

Q8: Do you agree with the process for the health board's publishing of its assessment?

Yes. We support transparency and evidence-based approaches to the planning of pharmaceutical services. The minimum time for consultation of 60 days must be incorporated into the planning process and accounted for in the initial introduction of PNAs. We believe that as a minimum, the 60 days period must be added to the initial timescale of six months for producing the first PNAs from enactment of the 2020 regulations. We are concerned that the development of PNAs must be given adequate time and more than 6 months from enactment of the 2020 regulations to ensure a comprehensive, robust and effective PNA can be produced. Ideally we would recommend that this timeframe should be increased to 12 months (\*See answer to question 26 below)

Q9: Are there any other factors a health board should have regard to when making an assessment?

We agree with the list of other factors a health board should have to consider as outlined in the draft regulations. We would also recommend that the health and social care needs assessments, undertaken by Regional Partnership Boards, are also considered as part of this process to ensure a robust evaluation of population need. Pharmaceutical services are increasingly becoming an important part of the social care agenda and it is important that PNAs also consider social care needs.

Q10: Do you consider it appropriate to maintain existing pharmaceutical and dispensing doctor lists when the 2020 Regulations come into force?

Yes. It is important for Health Boards to understand precisely the services provided by their contractors in their areas. Effective service gap analyses to contribute to PNAs and to ensure the development of pharmaceutical services will depend upon accurate and up to date lists.

Q11: Do you agree to the maintaining of previously defined controlled areas?

No comments.

Q12: Do you consider the change of test as a consequence of the introduction of pharmaceutical needs assessment to be appropriate?

Yes. We agree that any changes to the provision of pharmaceutical services and applications to supply such services must meet the service and population needs as identified in the PNA.

Q13: Are there any other criteria that should be applied to this test?

No Comments.

Q14: Do you agree with the removal of minor relocations for premises?

No. We support flexibility in the 2020 regulations to allow minor relocations for premises to take place provided the proposed relocation meets population needs and can provide improved access to services for the public and patients as defined and identified in the PNA.

Q15: Do you consider a move between health board areas should only be allowed when a need has been identified in the health board's assessment and providing it does not disadvantage access by persons accustomed to accessing services in the current location?

Yes. We support the proposal only in the circumstances that the move between health board areas does not impact adversely on patient care and only when access to services is increased as a result of the move.

Q16: Do you have any comments to make on this consequential amendment?

We would support the removal of the 30 day requirement to receive comments on the temporary relocation of premises provided it has no adverse impact on patient care in the locality.

Q17: Do you have any comments on the criteria relating to inclusion in the list under specific conditions?

No Comments.

Q18: Do you have any comments in relation to local dispute resolution prior to the issuing of remedial notices?

We welcome the measures regarding dispute resolution and the issuing of remedial notices on the basis of underperformance. We believe this will support good practice and drive up quality standards for community pharmacy NHS services. The measures appear reasonable and fair as they are currently presented.

Q19: Is there any other information a remedial notice should contain?

No Comment.

Q20: Are the terms under which the health board may withhold payment for a breach of services appropriate?

No comments – these are contractual arrangements and RPS is not best placed to comment.

Q21: Do you have any comments about the process of remedial and breach notices?

No Comments.

Q22: Do you have any comments on the criteria for removal from the pharmaceutical list in relation to performance matters?

To ensure the delivery of quality care that the public can be assured of in Wales, we support measures to remove an NHS pharmacist or NHS appliance contractor from a pharmaceutical list where the contractor has breached their terms of service or failed to take steps to protect the safety of any person to whom the contractor provides pharmaceutical services. We support the emphasis contained in the draft 2020 regulations that any removal from the list must be justifiable and proportionate to the seriousness of any breach.

Q23: Do you have any comments with regard to appealing health board decisions in relation to performance matters?

No Comments.

Q24: Do you agree with this 'stand still' concept and these time scales?

No Comments.

Q25: Are there any unintended consequences created by the draft regulations you can foresee?

Overall we welcome the proposed regulations and believe they will have positive effect of improving the planning and delivery of pharmaceutical services by ensuring Health Boards robustly consider the pharmaceutical needs of their local populations and align services more closely with them.

Q26: Are there any additional points you would like to make regarding the proposals set out in the draft regulations?

We are concerned about the tight timescale to produce the first PNA and consider 6 months from enactment of the regulations in Wales will be problematic. We are aware that the timescale for introducing PNAs in England was 12 months and strongly recommend that the same timeframe is adopted in Wales. The risk of the 6 month timeframe is the development of rushed and suboptimal PNAs which could have a negative impact on pharmaceutical service provision and access to services.

Q27: We would like to know your views on the effects that the draft regulations would have on the Welsh language, specifically on opportunities for people to use Welsh and on treating the Welsh language no less favourably than English.

What effects do you think there would be? How could positive effects be increased, or negative effects be mitigated?

We feel strongly that use of the Welsh language in the delivery of pharmaceutical services is vitally important, not only to treat Welsh speakers with dignity and respect, but also to ensure patient safety. Pharmacists must be able to serve the language needs of their local communities, including the provision of patient consultations, the dispensing of prescriptions, and labelling through the medium of the Welsh language, where practicable. If Welsh is the language of choice of a patient, their needs must be respected and every effort made to support the patient – every patient should be treated with courtesy and respect to avoid potential discrimination. Where there is a significant need identified for Welsh language provision in the delivery of community pharmacy services, there must be adequate Welsh language provision to mitigate any negative effects and to improve the patient experience.

We would consider that PNAs should be translated into Welsh to comply with the Welsh Language Act 1993. As such, it is important that translation time is also incorporated into the timescale for LHBs to complete and publish their PNAs. We would add to the points made in our answer to question 26 that the six month deadline for the production of PNAs following the enactment of the regulations will need to be extended to 12 months to allow for translation of the PNAs into Welsh to be taken into account.

Q28: Please also explain how you believe the proposed regulatory provisions could be formulated or changed so as to have positive effects or increased positive effects on opportunities for people to use the Welsh language and on treating the Welsh language no less favourably than the English language, and no adverse effects on opportunities for people to use the Welsh language and on treating the Welsh language no less favourably than the English language.

\*Please see response to Q27.

Q29: 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:

No additional comments.

Responses to this consultation will be made public in a report and published on the Welsh Government's website.

If you would prefer your response to remain anonymous, please tick here: