

Terms of Reference

Four Nations Pharmacy Assurance Working Party

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Author:	Anoushka Tepielow
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1. Introduction

The Four Nations Pharmacy Assurance Working Party has been established to ensure that expert input is received in order to allow the Pharmacy Assurance project to progress as a collaborative, robust and streamlined process across the UK. The Working Party will discuss and agree upon technical aspects of the project and any problems arising, escalating any risks to each nation's respective authorities. The Working Party is accountable to the Four Nations Policy Leads Group and additionally has reporting structures within each nation:

- England – HRA Technical Assurance Project Team / Department of Health
- Northern Ireland - HSC R&D Division, Public Health Agency (PHA)
- Scotland - NHS Research Scotland (NRS) / Chief Scientist Office (CSO)
- Wales – Health and Care Research Wales Change Management Group

Other management groups, in each of the nations, may be linked into for recommendations and risk review.

2. Membership and Chairing

The Four Nations Pharmacy Assurance Working Party will be chaired by the HRA Technical Assurances Manager. In the absence of the Chair, a nominated representative from the HRA assessment and assurance team may act as Chair for that meeting.

Membership of the Four Nations Pharmacy Assurance Working Party is agreed by the Working Party and ratified by the Four Nations Policy Leads Group on the recommendation of each nation's governance arrangements. The composition of the Four Nations Pharmacy Assurance Working Party and team members who are required to attend by invitation are given in [Appendix A](#).

Members may send deputies by exception only. The HRA technical assurance team will support the provision of the secretariat function for this working party.

3. Quorum

A quorum shall consist of three expert members from any of the participating nations, all of which must be external to the Health Research Authority. Where an expert member is unable to attend, a nominated deputy may attend on their behalf. The deputy's information (to include name and role) must be submitted to either the Chair or Secretariat prior to the meeting commencing.

The Secretariat must advise the Chair or their deputy if there is risk of the meeting being inquorate. It is the responsibility of the Secretariat to know what the quoracy requirements are and must have this information available prior to the Four Nations Pharmacy Assurance Working Party meeting so that the Chair is able to make a decision as to whether the meeting should go ahead.

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If the meeting is inquorate, and/or both the Chair and their deputy are not in attendance, the meeting can go ahead as planned and minutes are taken. However, any decisions or actions taken at the meeting must be ratified either at the next meeting or out of session if urgent.

4. Frequency of Meetings

Meetings will be held monthly usually by teleconference. Ad hoc meetings, or informal sub-group meetings, may be held by agreement of the Chair as and when required so that the work can continue at pace. Meetings may, exceptionally, be cancelled by the Chair.

There may occasionally be a need for Chair's action in order to finalise matters which have already been discussed. Any Chair's action taken between meetings are to be recorded in the minutes of the next meeting.

The Four Nations Pharmacy Assurance Working Party will be responsible for providing advice on the development, delivery and roll out of Pharmacy Assurance UK-wide. Specifically it will:

- 4.1 Advise on the strategic direction for the further development and implementation of Pharmacy Assurance across the UK.
- 4.2 Agree and advise on key technical principles and processes for Pharmacy Assurance implementation, taking into consideration UK-wide systems. Advice may also be given on operational aspects of the project.
- 4.3 Receive and review reports from the HRA technical assurance team on the progress of the project, ensuring management and mitigation of risks, providing feedback, support and challenge as appropriate.
- 4.4 Work with the Four Nations Policy Leads Group and project boards and/or teams within the HRA, to ensure a single direction of project development, reduce conflicting actions and minimise any duplication of resources. The Four Nations Pharmacy Assurance Working Party may discuss matters for which decision making responsibility lies elsewhere and these should be taken to the appropriate decision making body by the Chair.
- 4.5 Report to the relevant UK groups on the progress of the project. This includes, but is not limited to the:
 - Four-Nations Policy Leads Group
 - HRA Technical Assurances Project Team (reports to the HRA Technical Assurances Project Team will be made monthly)
 - Northern Ireland - HSC R&D Division, PHA
 - Scotland – NRS / CSO
 - Wales – Health and Care Research Wales Change Management Group

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- 4.6 Review the risks associated with the project, escalating to each Nation's respective authorities, along with any proposals for changes to plans, priorities or resources that would address identified risks.

HRA technical assurance team members attending the meetings, most especially the Technical Assurances Manager, have a specific role to play in ensuring consistency across the HRA project boards and/or teams and identifying matters that have fallen between the responsibilities of the boards and/or teams.

5. Freedom to Act

The Four Nations Pharmacy Assurance Working Party has the authority to modify plans or alter priorities within this workstream only where there are no interdependencies to plans or priorities for other workstreams, or where failure to modify plans or priorities would put the programme delivery at risk. The Four Nations Pharmacy Assurance Working Party does however have the authority to propose changes to plans and priorities to the Four Nations Policy Leads Group and has a responsibility to do so and to highlight identified interdependencies with other workstreams. The Four Nations Pharmacy Assurance Working Party does not have the authority to add or remove resources allocated to the workstream but has a responsibility to propose changes to the Four Nations Policy Leads Group. The Four Nations Pharmacy Assurance Working Party cannot authorise expenditure but has a responsibility to propose requirements to each nation's respective authorities.

6. Reporting

The Four Nations Pharmacy Assurance Working Party will report to each nation's respective authorities and to the Four Nations Policy Leads Group. Each national authority will have its own mechanism for escalating issues, for example, in England issues may be drawn to the attention of the HRA Approval Service Workstream Steering Group, to the HRA Leadership Team and /or HRA Board.

The minutes of these meetings will be formally recorded and available to the relevant respective authorities upon request. When approved by the Four Nations Pharmacy Assurance Working Party the minutes will be made available on the HRA shared drive. Occasionally, when the minutes contain information that it is not in the public interest to publish, this content will be contained within a part 2 section of the minutes which is confidential.

7. Papers

Agenda items may be raised by any member of the Working Party and should be communicated to the secretariat at least seven working days in advance of any meeting.

All papers for the Working Party meetings will be circulated to Working Party members at least five working days in advance of meetings.

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Draft minutes of each meeting will be circulated within seven working days to Working Party members for comment and will provide a clear record of decisions reached and actions agreed.

Minutes will be formally approved by the Working Party at the subsequent meeting.

The secretariat will maintain an action log, which will be circulated to Working Party members within seven days of a meeting occurring. These will also be reviewed at each meeting.

8. Review

The terms of reference should be reviewed at least annually.

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9. Appendix A: Document Control

Origin and Responsibility

Author	Project Name
Anoushka Tepielow	Four Nations Pharmacy Assurance

Change History

Version	Status	Changes
0.1	DRAFT	Document creation
0.2	DRAFT	Clarifying roles of members and reporting arrangements
0.3	DRAFT	Spelling and grammatical changes
0.4	DRAFT	Amending internal HRA reporting arrangements Clarifying Working Party composition Grammatical changes
1.0	FINAL	Up-versioning to final version for publication on HRA website

Working Party Composition

Role	Job Title
MEMBERS	
Chair	Manager – Technical Assurances
Pharmacy Expert Representative - Wales	Principal Pharmacist Research, Development and Audit
Pharmacy Expert Representative - Scotland	Lead Pharmacist Clinical Trials
Pharmacy Expert Representative – Northern Ireland	Lead Clinical Trials Pharmacist, Belfast Health and Social Care Trust (BHSCT) Chairperson, Northern Ireland, Regional Pharmacy Clinical Trials Group
Pharmacy Expert Advisor - England	Lead Clinical Trials Pharmacist
IN ATTENDANCE	
Secretariat	Technical Assurance Officer

Distribution/Publication

This document will be published externally on the HRA website and will be available internally on the HRA shared drive.

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