ROYAL PHARMACEUTICAL SOCIETY

Professional standards, guidance and frameworks process development manual

NICE has accredited the process used by the Royal Pharmaceutical Society to produce its professional guidance and standards. Accreditation is valid for 5 years from 17 February 2017.

For full details on NICE accreditation visit: www.nice.org.uk/accreditation

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About us

About this manual

This manual describes how the Royal Pharmaceutical Society develops professional standards, guidance and frameworks.

About the Royal Pharmaceutical Society (RPS)

The Royal Pharmaceutical Society (RPS) is the professional body for pharmacists in Great Britain constituted by Royal Charter representing all sectors of pharmacy in Great Britain and leading the support and development of the pharmacy profession including the advancement of science, practice, education and knowledge in pharmacy..

The structure and governance of the Royal Pharmaceutical Society is detailed in our governance handbook which is available online.

About RPS professional standards, guidance and frameworks

The objectives of Royal Pharmaceutical Society (RPS) professional standards, guidance and frameworks are to:

- Describe good practice, systems of care or working.
- Provide a broad framework to support pharmacists and their teams to develop their professional practice, improve services, shape future services and deliver high quality patient care across all settings and sectors.
- A framework to help commissioners and those contracting services to design, implement, deliver and monitor high quality practice through pharmacy
- To support the development and delivery of consistently high quality services and evaluation of those services
- Be supportive, enabling and professionally challenging.

The topics and questions addressed by our standards typically apply to different healthcare settings delivering pharmacy services or describe best practice applicable to pharmacy activities related to medicines.

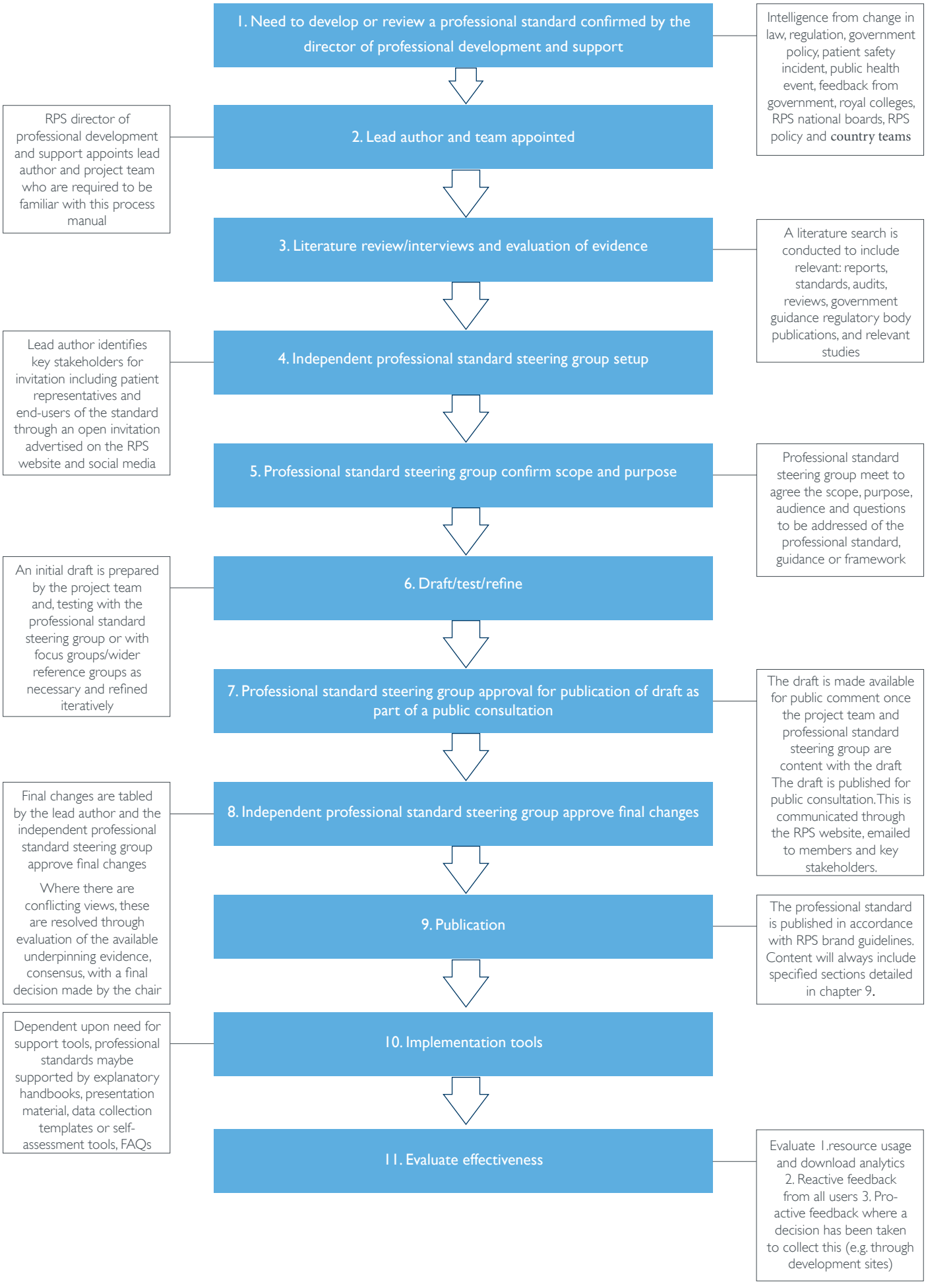
How the RPS is funded

The RPS annual review available on the RPS website. The RPS is mainly funded by membership subscription and publication activities of Pharmaceutical Press. From time to time, the RPS may be commissioned by the government to undertake research or develop reports. http://www.rpharms.com/about-us/annual-review.asp

Statement of editorial independence

Professional standards, guidelines and frameworks developed through this process are evidence-based and editorially independent. This process safeguards the editorial independence of the professional standards steering group from the funding body and conflicts of interest.

RPS professional standards development process



1. Identifying need to develop or review a professional standard, guidance or framework

The need to develop or review a professional standard, guidance or framework and questions to be addressed may be identified from multiple source of intelligence and a decision to progress is confirmed by the director of professional development and support.

Sources of intelligence

- Change to legislation, regulation, government policy or
- Patient safety or public health incidents
- Feedback from pharmacists and the pharmacy team
- Feedback from government, royal colleges, other pharmacy organisations, other healthcare professionals, patients and patient groups
- RPS campaigns and policy priorities led by the RPS national boards for England, Scotland and Wales

The topics addressed by our standards typically include the delivery of pharmacy services through different healthcare settings or pharmacy activities related to medicines.

2. Appointing the lead author and project team

The RPS Director for Professional Development and Support appoints the lead author and project team.

The lead author may be any RPS member of staff, secondment colleague or externally commissioned.

A copy of the RPS professional standards, guidance and frameworks process development manual is provided and it is required that the lead author and project team are familiar with the process.

3. Literature review and evaluation of evidence

The literature review can be conducted by the lead author or external contractor.

The methodology for the literature review is as follows:

I. Identify search question

II. Identify inclusion and exclusion criteria

III. From the search question, identify key words, spelling variations, synonyms and associated terms

IV. Using the search question and key words, check the following

Document type with link to topic area	Publisher
a. Legislation b. Standards c. Guidance d. Reports e. Audits f. Reviews g. Studies and published trials	a. UK or developed government b. UK or GB regulatory bodies, including healthcare regualtory bodies c. UK or GB healthcare organisation, Royal College, non-government organisation (NGO) or registered charity d. European Union (EU) or EU decentralised agency (such as the European Medicines Agency) etc e. International Pharmaceutical Federation (FIP) f. International government, healthcare or pharmacy regulatory or professional body g. Catalogued bibliographic databases (where applicable) • International pharmaceutical abstracts • Medline • Cinahl • Biomedical Reference Collection corporate edition

V. Where the topic of the standard is not supported by published literature or grey literature, consider conducting interviews with key stakeholders to obtain expert opinion

VI. Record the date of the search

Evaluation of evidence

Documents and studies and data collected from the literature review process are evaluated against the inclusion and exclusion criteria and then discussed between the person conducting the literature review and the project lead, bearing in mind the Scottish Intercollegiate Guidelines Network (SIGN) grading system 1999-2012 which uses the following hierarchy of levels of evidence.

1++	*High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk bias*
1+	*Well-conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias*
1-	*Meta-analyses, systematic reviews, or RCTs with a high risk of bias*
2++	*High quality systematic reviews of case control or cohort or studies* *High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal*
2+	*Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal*
2-	*Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal*
3	*Non-analytic studies, e.g. case reports, case series*
4	*Expert opinion*

4. Setting up the independent professional standard steering group

Constitution

The professional standard steering group is chaired by the lead author or a nominee appointed by the RPS director for Professional Development and Support.

The chair may not have a conflict of interest in the topic area and is responsible for ensuring that all other members of the professional standard steering group have declared relevant interests. The chair does not need to have expertise in the topic area but should have experience chairing meetings.

The lead author will oversee the publication on the RPS website and via social media of an open invitation for people to become part of the independent professional standards steering group. Where a suitable lay representative does not respond to the advert, one may be sought and found through National Voice.

The lead author will oversee the process to identify who to invite to join the steering group. This should include where practicably possible a representative range of stakeholders including:

Lay people, representative of beneficiaries of the services underpinned by standard/guidance/framework

Users of the guideline, e.g. pharmacists and pharmacy teams or other members of the healthcare team currently working in the topic area at a practical, management and strategic level across the different sectors linked to the topic area

Representatives of organisations or networks with a link to the topic area including pharmacy or healthcare organisations

Pharmacists with a recognised national or international leadership role or expertise in the topic are

The lead author will contact the list of people for invitation using the template invitation wording a completed terms of reference template a declaration of interests templates and a copy of the RPS professional standards, guidance and frameworks process manual.

Role

The role of the professional standard/guidance steering group is to:

- Confirm the purpose and scope of the standard, guidance, framework
- Confirm the questions to be addressed by the standard, guidance, framework.
- Working with the lead author and project team, contribute and review content throughout the development of the standard

- Consider and provide opinion on the wider impact and implications of the professional standards/guidance developed
- Review iterations of the standard/guidance and comment on specific issues identified by the project lead
- Reviews and sign off the final version of the guidance.

The professional standard steering group may discuss and decide issues by email, teleconference, or face-to-face, meetings as needed.

Managing conflicts of interest

All members of the independent professional standard steering group including the chair are required submit completed declarations of interests and to agree to participate under the terms of reference before serving on the professional standard steering group.

Declarations of interest are collated by the project team and these will be made available upon request.

At the start of each meeting the Chair will ask the group to confirm any changes to declarations of interest. It then is at the discretion of the Chair whether the individual member declaring an interest may take part in the discussion, remain for the discussion, but not take part or vote, or should leave the meeting for the duration of the item. Declarations of interest and the decision of the Chair on how the declarer will take part in the meeting will be noted in the minutes.

Decisions of the professional standard steering group

Drafts are developed and refined through consensus of the professional standard steering group in the context of the evidence-base from the literature review and evaluation, the circulation for comment together with the agreed scope and purpose of the professional standard.

All members of the professional standard steering group are given the opportunity to speak to present their views, including on issues of disagreement.

Where consensus cannot be reached prior to public review the issue of conflicting views or lack of evidence should be specifically highlighted and reviewed as part of the public and peer review process.

Where consensus cannot be reached post public and peer review, the issue should be resolved through a vote of the professional standard/guidance development steering group. Dissenting views should be recorded in the minutes, and where appropriate within the final published standard.

The professional standard steering group should discuss:

- From a patient perspective, the benefits and the risks or unintended consequences of the recommendations made
- Organisational and financial barriers to implementation

A summary of these should appear in the final draft.

5. Confirming the scope and purpose of the professional standard

The scope, purpose and intended audience of the professional standard are confirmed at an initial meeting of the professional standard/guidance steering group and included within the final document

- Purpose of professional standard
- Scope of professional standard
    - Including exclusions from scope
- Intended audience of the professional standard
- The questions to be answered by the guidance

6. Developing the professional standard and refinements

The first draft is developed by the lead author and project team with consideration to:

I. The evaluation of results from the literature or grey literature review

II. Agreed purpose, scope, audience and questions to be addressed

III. Ensuring that the language used is suited to the target audience. This will usually be pharmacists and pharmacy teams, and occasionally the wider multi-disciplinary healthcare team. RPS professional standards, guidance and frameworks are not developed for a patient audience.

IV. The impact, risks and benefits of the recommendations within each professional standard

V. Different options that can be used to meet the recommendations within the guideline, framework or standard. E.g. professional standards are outcome focussed and there may be a range of options to achieve these outcomes

The draft is refined through feedback and comment of the professional standard steering group. In some cases additional expertise will be needed and depending upon the issues small focus groups or a wider reference group of stakeholders can be setup by the project lead to provide additional feedback and testing of drafts. These will include representative users of the standard./guidance/framework e.g. users currently working in the topic area at a practical, management or strategic level.

7. Public consultation

The draft is iteratively refined until the professional standard steering group agree the draft is ready for public consultation.

The draft is published on the RPS website (www.rpharms.com) and made available for and open-access consultation to any interested party for a period of 4-6 weeks.

Key stakeholder organisations are made aware of the public consultation by email and press release and invited to respond. Key stakeholders vary between work programmes and may include:

- Pharmacists and pharmacy professionals
- Patient groups and patient charity representatives
- NHS groups
- Royal Colleges
- Pharmacy Academics
- Government bodies, regulators and relevant executive agencies
- Other healthcare professionals

The project team monitors responses to the public consultation and will intervene to send reminders or to seek additional views if comments are not received from the public consultation.

8. The final draft

When the consultation period has ended, the project team will collate feedback from the consultation, analyse and revise the document. Tracked changes are marked and the document is shared with the professional standard/guidance steering group.

The project team will evaluate the feedback and make refinements to the standards/guidance.

The independent professional standard steering group will be asked to discuss changes, areas of conflicting feedback and to approve the final draft for publication.

9. Publication

The professional standard/guidance is formatted and published as an open-access document on the RPS website.

How our standards are formatted

Each standard should meet RPS brand guidelines and content should include the following sections:

- Title page
- Publication date
- Review date
- Foreword
- Contents page
- Purpose and scope of standard
- Intended audience

- Summary of professional standards
- Detail of professional standards
- Acknowledgements
- Summary of methodology
- Summary of search strategy
    - Inclusion and exclusion criteria
    - Date of evidence search
- Summary of benefits and risks
    - Including unintended consequences of the recommendations made.
    - Financial and organisational barriers to implementing the recommendations
- RPS contact details

10. How we support implementation of our standards

Publication of the standard is promoted by a communications programme delivered through:

- Press release and social media through the RPS media team and press officer
- Communications to all RPS members through the RPS membership and marketing team
- Emailed communications to key stakeholder organisations with an interest in the topic area
- RPS local practice forums

Support tools are developed to aid implementation of our standards, these can include:

- Handbook guidance documents
- Self-assessment templates and data collection forms
- Power-point presentations
- Frequently asked questions
- Case-studies
- Webinars
- Checklists

The RPS professional support service, an enquiry service accessible by phone and email is also available to members of the RPS with day to day queries about standards, guidance and frameworks.

Financial and organisational barriers to implementation will have been discussed by the professional standards steering group and a summary included within the final draft.

11. How we measure effectiveness of our standard

Effectiveness of our standards, guidance and frameworks are measured in a variety of ways including:

1. The RPS has access to analytics data for web-page and professional standard download statistics
2. Where development sites are testing the professional standards in practice, feedback will be pro-actively collated and analysed
3. The RPS reactively collates qualitative feedback from all users of the standard for future review by the project team and contact details are available on all our standards
4. Use or reference to standards, guidance, frameworks by NHS, health or training systems e.g. NHS benchmarking reference to Hospital Standards and CPPE reference to Public Health Standards

Review of the standard

Triggers for review include:

- Routine review four years after publication.
- Patient safety or public health incident prompting the need for an unscheduled review of standards, depending upon the issue, a report may be commissioned
- Change in legislation, regulation, practice or feedback from users

Our approach to standards, frameworks, guidance review is detailed below:

Scoping

- Review in the context of the trigger
- Consider commissionied report or literature search to identify ommissions or changes required

Review of recommendations

- Steering group held to review the report and recommendations
- Modifications to the original standard/framework/guideline agreed

Updating

- Standard/framework/guideline updated
- All changes tracked to facilitate review

Circulation for comment

- Refined standard/framework/guideline (tracked) circulated for comment
- Circulated to steering group and all other stakeholders involved in original standards development
- Public consultation

Reviewing and updating

- Comments reviewed and standard/framework/guideline refined
- Final refinements sent to the steering group for review

Sign off & Launch

- Standard/guideline/framework updated
- Publication on RPS website and communications to all stakeholders

Appendices

Professional standard steering group invitation letter or email wording

Dear .....

We are pleased to announce that the Royal Pharmaceutical Society is establishing a steering group to help us develop professional standards/guidance for .....

The guidance/standards aim to support.....

The steering group will support the work of the RPS by providing a source of expertise on.....

We would like to invite you to be a member/nominate a representative of your organisation to be a member of the professional standard steering group.

The group will typically meet formally face-to-face [.....] over the duration of the project; Additional meetings will be scheduled as required and may be conducted via teleconference, webinar or email discussion.

The first meeting will be on ..... Other meetings will be scheduled at the first steering group meeting. I have attached a draft Terms of Reference for the group and a Declaration of interest form.

I do hope you are able to join this steering group and look forward to hearing from you in due course. If there are any queries about the group feel free to contact .....

Kind regards

.....

Declaration of Interests

I declare that the interests recorded below include each and every interest, which might be considered to have a potential to influence the exercise of impartial judgement by me in my connection with the Royal Pharmaceutical Society.

Name _____

Signature _____

Date _____

Please record your interests under the appropriate heading in the table below.

1. Remuneration

List the names of any organisations (including your present employer) from which you currently draw a salary or other remuneration including honoraria, long-term or regular consultancies, and any directors' fees or other emoluments from private companies or PLCs. Short-term or one-off consultancies which are associated with your advice to the Royal Pharmaceutical Society should be declared. In no case are you expected to disclose the level of salary or other payments.

2. Directorships

List the names or any private companies or PLCs of which you are currently a director, or of which you have been a director at some point during the last three years, or of which you expect to become a director within the next year (whether paid or unpaid). You are not expected to disclose the level of any directors' fees or other emoluments.

3. Significant Share-Holdings

List the names of any companies or businesses – whether private or publicly-quoted – in which you hold a significant share-holding. 'Business' should be taken to include consultancies, partnerships and the like; you will be deemed to have a 'significant share-holding' if you own more than 5 per cent or more of the business (normally 5 per cent or more of the issued share capital). You are not expected to disclose the level of your financial interest in these companies or businesses.

4. Unpaid activities

List the names of any unpaid offices you hold – for example, in a company, higher education institution, charity or voluntary or public body – which you consider might have a bearing on your role. You should include any charity trusteeships you hold, or any other way in which you participate in the management of a charity.

5. Political Pressure Groups or Associations where their objectives are related to the activities and objects of the Royal Pharmaceutical Society

6. Family Interests

List any interests you have through your members of your family having interests which might be considered to have a potential to influence the exercise of impartial judgement by you in your connection with the Royal Pharmaceutical Society.

Terms of Reference

The terms of reference will include the following headings:

- Background
- Purpose of the Steering Group
- Functions
- Accountability
- Duration
- Commitment
- Membership of the group

Professional standards, guideline, framework development checklist

RPS director or assistant director of professional support and developed have reviewed the conflict of interest declaration of the lead author/chair	◯
Details of the search criteria including date of evidence search, inclusion and exclusion criteria are described within the final document or supporting documents/web resources	◯
There has been an open invitation on the RPS website and through social media inviting stakeholders to join the independent professional standards steering group	◯
Patients or patient groups are represented on the independent professional standards steering group	◯
Representative end-users of the standard, guidance, framework are included within the independent professional standards steering group	◯
Representatives of key organisation with links to the topic area have been included in the independent professional standards steering group	◯
Declarations of interests for all members of the independent professional standards steering group have been collected and available upon request	◯
All members of the independent professional standards steering group have agreed to work under the terms of reference and are aware of the RPS professional standards, guidance and framework process manual	◯
The independent professional standards steering group have agreed the purpose, target audience, and questions to be addressed by the standards and these are clear within the document	◯
The independent professional standard steering group have discussed barriers and unintended consequences of recommendations including financial and organisational	◯
There has been a public consultation open to interested parties	◯
There have been sufficient responses to the consultation to inform development	◯
In the rare event of unresolved dissenting views of the professional standards steering group. Have these been considered for acknowledgement within the final document	◯
The language used within the document is suitable for the intended audience	◯
The standards, guidelines, framework are clear and unambiguous	◯
There are specific examples within the document describing how the recommendations will be supported through implementation	◯
Publication, amendment and review dates are current and published on the final document	◯

About Us

The Royal Pharmaceutical Society (RPS) is the professional body for pharmacists and pharmacy in Great Britain. We represent all sectors and specialisms of pharmacy in Great Britain and we lead and support the development of the pharmacy profession to deliver excellence of care and service to patients and the public. This includes the advancement of science, practice, education and knowledge in pharmacy and the provision of professional standards and guidance to promote and deliver excellence. In addition we promote the profession's policies and views to a range of external stakeholders in a number of different forums.

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