|  |
| --- |
| **Checklist for submitting comments*** Use this comments form and submit it as a **Word document (not a PDF)**.
* **Do not submit further attachments** such as research articles, or supplementary files. We return comments forms that have attachments without reading them. You may resubmit the form without attachments, but it must be received by the deadline. You are welcome to include links to research articles or provide references to them
* Complete the disclosure about links with, or funding from, the tobacco industry.
* Include **document name,** **page number and line number** of the text each comment is about.
* Combine all comments from your organisation into 1 response form. **We cannot accept more than 1 comments form from each organisation**.
* **Do** **not** paste other tables into this table – type directly into the table.
* Ensure each comment stands alone; **do not** cross-refer within one comment to another comment.
* **Clearly mark any confidential information or other material that you do not wish to be made public with underlining and highlighting. Also, ensure you state in your email to NICE, and in the row below, that your submission includes confidential comments.**
* **Do not name or identify any person or include medical information about yourself or another person** from which you or the person could be identified as all such data will be deleted or redacted.
* Spell out any abbreviations you use.
* **We have not reviewed the evidence for the recommendations shaded in grey. Therefore, please do not submit comments relating to these recommendations as we cannot accept comments on them.**
* **We do not accept comments submitted after the deadline stated for close of consultation.**

**Note:** We reserve the right to summarise and edit comments received during consultations, or not to publish them at all, if we consider the comments are too long, or publication would be unlawful or otherwise inappropriate. Where comments contain confidential information, we will redact the relevant text, or may redact the entire comment as appropriate.Comments received during our consultations are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the comments we received, and are not endorsed by NICE, its officers or advisory Committees.  |

|  |  |
| --- | --- |
|  | **Please read the checklist above before submitting comments.** **We cannot accept forms that are not filled in correctly.** We would like to hear your views on the draft recommendations presented in the guideline, and any comments you may have on the rationale and impact sections in the guideline and the evidence presented in the evidence reviews documents. We would also welcome views on the Equality Impact Assessment.In addition to your comments below on our guideline documents, we would like to hear your views on these questions. **Please include your answers to these questions with your comments in the table below.**1. Would it be challenging to implement of any of the draft recommendations? Please say why and for whom. Please include any suggestions that could help users overcome these challenges (for example, existing practical resources or national initiatives.
2. Would implementation of any of the draft recommendations have significant cost implications?

See [[Developing NICE guidance: how to get involved](https://www.nice.org.uk/process/pmg20/resources/developing-nice-guidelines-how-to-get-involved-2722986687/chapter/commenting-on-a-draft-guideline)](https://www.nice.org.uk/process/pmg20/resources/developing-nice-guidelines-how-to-get-involved-2722986687/chapter/commenting-on-a-draft-guideline) for suggestions of general points to think about when commenting. |
| Organisation name (if you are responding as an individual rather than a registered stakeholder please specify). | Royal Pharmaceutical Society |
| Disclosure (please disclose any past or current, direct or indirect links to, or funding from, the tobacco industry). |  |
| Confidential comments (Do any of your comments contain confidential information?) | No  |
| Name of person completing form | Heidi Wright |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Comment number** | **Document**[e.g. guideline, evidence review A, B, C etc., methods, EIA] | Page number**‘General’** for comments on whole document | Line number**‘General’** for comments on whole document | Comments* Insert each comment in a new row.
* Do not paste other tables into this table, because your comments could get lost – type directly into this table.
* Include section or recommendation number in this column.
 |
| 1 | Guideline | General | General | We welcome the updating of the 2015 guidance. Individualising care for people experiencing menopausal symptoms and explaining all available treatment options is essential and we are pleased to see this emphasised in the guidelines. The guidance demonstrates a growing recognition of the complexities and unique challenges faced by women during menopause. The inclusion of comprehensive, evidence-based recommendations in this guideline reflects a commendable effort to improve the quality of care for women experiencing menopausal symptoms |
| 2 | Guideline | General | General | More emphasis on CBT to help alleviate some menopausal symptoms is well placed. |
| 3 | Guideline | General | General | It is good to see genitourinary symptoms mentioned alongside a variety of treatment options. |
| 4 | Guideline | General | General | Further areas for research have been identified and we agree with these priority areas. |
| 5 | Guideline | General  | General | More support is needed to ensure all healthcare professionals have a general understanding of the menopause. |
|  | Guideline | General | General | We welcome the tables: Combined HRT: effect on health outcomes and Oestrogen-only HRT: effect on health outcomes. They will be very useful in practice |
| 6 | Guideline | 7 | 12-14 | It would be helpful to have the NHSE endorsed Selfcare Forum Menopause PIL cross referenced here for health professionals to use in consultations. It would be good if this PIL was available in different languages to ensure inclusivity. |
| 7 | Guideline | 11 | 7-13 | We note that there are already long waiting lists and capacity issues with CBT services for patients with mental health or malignancy indications. We would welcome NICE NG23 updated guidance indication that menopausal anxiety and depression needs are a priority indication. Considering the evidence base review for CBT as outlined within the consultation document, the focus should include patient profiles such as clinical depression and menopausal anxiety and depression; cancer and menopause anxiety and depression.  |
| 8 | Guideline | 12 | 11-14 | There is a need for NICE guidance on HRT dosing regimens that maybe required for treatment of menopause symptoms in Trans Men and Non-binary people registered female at birth. The updated guidance when published in 2024 will raise expectations in this group for HRT treatment. Experience within clinics indicate that even if these patients are off GAT they feel that they need higher HRT dosing. We welcome the recommendation for research in these patient groups; however, guidance on prescribing should be considered now. |
| 9 | Guideline | 13 | 1-12 | We would suggest a change in the sentence as follows - ...initiated on recommendation by a health professional with expertise in menopause. There are already capacity issues as specialists are dealing with COVID backlogs. The expectation that the first prescription is issued by the menopause specialist will have ramifications on capacity and affect patient care adversely due to long waiting times. We suggest that initiation is not limited to a menopause specialist. |
| 10 | Guideline | 13 | 27-29 | Consider the evidence base for TAH with RRBSO recommendation for management of familial and genetic risk of ovarian cancer as unopposed oestrogen is associated with a lower increase in risk for breast cancer vs combined HRT, associated with higher breast cancer risks [but combined HRT would need to be offered if the patient has only had a BSO].  |
| 11 | Guideline | 16 | 14 | Clarify text and add in that vaginal oestrogen is contra-indicated in women with breast cancer on aromatase inhibitors - in line with statement 1.4.30 |
| 12 | Guideline | 18 | 3-8 | The guideline addresses vaginal dryness, a common and distressing symptom of menopause. It's encouraging to see that treatments for this condition are now more accessible, being available over the counter in local pharmacies. This could be highlighted more clearly within the guideline. This not only enhances access for women but also helps to reduce the burden on general practice appointments, a crucial factor in improving healthcare efficiency and patient experience. |
| 13 | Guideline | 19 | 15 | Unopposed oestrogen is prescribed with TAH but with complex cases eg TAH and severe endometriosis or subtotal hysterectomy, these patients can be / would be advised to use combined HRT [ref Cochrane database; Post Reproductive Health publications 2022.]  |
| 14 | Guideline | 22 | 3 | As per the French EN3 study, both micronized progesterone and dydrogesterone are considered as proffering lower breast cancer risk increase and should be stated in the updated guidance as there are patient profiles who do not settle on micronized progesterone and side effects mean that a suitably low risk alternative option for endometrial protection needs to be offered. Dydrogesterone, a progestogen used in hormone replacement therapy (HRT), is perhaps not as widely utilised as it could be. The EN3 Study sheds light on the effectiveness and safety profile of dydrogesterone, suggesting it could be a valuable option for many women. Inclusion in the NICE guideline would be a positive development, bringing attention to a potentially underused treatment option. |
| 15 | Guideline | 37 | 16 - 28 | This section looks at the definition of a health professional with expertise in menopause. Many GPs consider themselves as having expertise in menopause but are not BMS accredited. They may have done additional training but may not fulfil all the BMS criteria and may not have expertise in all four listed specialist areas in lines 20-26. Perhaps rewording this section to be more accommodating would also resolve the workload concerns of the original draft guidance and our suggested amendment at number 9. |
| 16 | Guideline | 47 | 12-18 | The guideline helpfully clarifies that CBT has not been proven to help with low moods associated with menopause status. An explicit statement would be useful for health professionals. |
| 17 | Guideline | 48 | 7-15 | Natural progesterone, with biological plausibility, is being researched independently for sleep problems, including insomnia and early wakening. Research for use in menopause and sleep should be a research recommendation. Qs include could natural progesterone be used on its own in postmenopausal women over 65 for sleep benefit? Does natural progesterone a part of HRT regimen improve menopausal sleep outcomes? |
| 18 | Guideline | 19 | 6-7 | Although this text is greyed out, we would suggest amending the sentence to say ‘for people with low sexual desire associated with the menopause and causing distress if HRT alone is not effective. While testosterone treatment can be beneficial for some women, especially those with low libido, the guideline needs to provide clearer direction for clinicians. The suggestion to optimise oestrogen treatment before prescribing testosterone is a prudent approach, and the guideline could benefit from a clear statement advising clinicians to seek further guidance or consider referral when low libido is suspected to be related to testosterone levels if they do not feel confident to make sure a diagnosis. Such guidance would undoubtedly enhance patient outcomes. |

Insert extra rows as needed

**Data protection**

The information you submit on this form will be retained and used by NICE and its advisers for the purpose of developing its guidance and may be passed to other approved third parties.Please do not name or identify any individual patient or refer to their medical condition in your comments as all such data will be deleted or redacted. The information may appear on the NICE website in due course in which case all personal data will be removed in accordance with NICE policies.

By submitting your data via this form you are confirming that you have read and understood this statement.

For more information about how we process your data, please see our [privacy notice](https://www.nice.org.uk/privacy-notice).