1. Introduction

1.1. Purpose: The purpose of public comment in the DERP process is to allow the public (e.g., pharmaceutical industry, advocacy groups, clinicians, patients) the opportunity to provide thoughtful and relevant feedback on reviews conducted by the Drug Effectiveness Review Project (DERP). There are two public comment periods for each DERP Review. The first period for public comment is at the draft key questions stage. The second period is at the draft report stage.

1.2. Notification of Public Comment Periods: The public is notified of public comment periods in three ways.

1.2.1. The public timeline for all DERP reports can be found on our website at http://www.ohsu.edu/xd/research/centers-institutes/evidence-based-policy-center/derp/index.cfm. This contains the dates when public comments (and other due dates of interest) are scheduled.

1.2.2. Requests for public comment are posted on the draft documents page of the website, http://derp.ohsu.edu/about/draft-document-display.cfm. This is where public comments are communicated using the form provided (see below).

1.2.3. The Center for Evidence-based Policy alerts known interested parties by email when a document has been posted for public comment. To be included in this notification, an interested party must provide their contact information to the Center for Evidence-based Policy. Contact information should be kept current and sent to the DERP administrative coordinator at sanborn@ohsu.edu.

1.3. Submission of Evidence: Your opportunity to provide evidence is during the dossier solicitation period after the key questions have been finalized.

2. General Instructions

2.1. Appropriate Comments: Please be courteous and professional when providing comments. Public comment forms are not the place to comment on the DERP or its process. If you have any questions, concerns, or comments regarding the Center, DERP, and/or the methods for reviews, please send us an email at centerebp@ohsu.edu. Any comments regarding issues unrelated to the document under consideration should be handled by separate correspondence; commenters should NOT use the public comment form associated with a specific draft document.
2.2. *Comment Types*: Comments on the public comment form are specified as either general, specific or a citation.

2.2.1. When providing comments on specific sections of the review, please indicate line/page number.

2.3. *Word Limits*: Word limits are attached to the public comment form to encourage brief, clear, concise, and constructive comments.

2.3.1. The overall word limit (general and specific comments combined) per person is 10,000.

2.3.4. *Comments exceeding the limits will not be accepted.*

2.4. *Repeating Comments*: Please do not repeat the same/similar comment more than once; it wastes time and adds nothing to the review.

2.5. *Comments that will not be considered*: Comments on general systematic review methods used across DERP reports should not be communicated using the public comment form. This type of comment should be communicated separately to the Center in writing or in person. The following comments will not be considered in the public comment period for any DERP review.

2.5.1. Any comments relating to the role of evidence in any decision-making process
2.5.2. Any comments on the way P&T committees use the DERP reviews
2.5.3. Any comments on the interactions between the Center or EPC and the participants of DERP
2.5.4. General comments about a drug that do not pertain to something specific in the draft document (i.e. marketing material, product insert, etc)

3. **Guidelines when commenting on key questions**

3.1. *Considerations for the commenter*: The public comment period for draft key questions is your opportunity to give input on the scope of a drug class review before the review begins. Please do not “answer” the draft key questions in your response. Please consider the following elements when commenting on the draft key questions. (You need not specifically answer the questions below, they are provided only as a guide).

3.1.1. Is the purpose of the review made clear by the key questions posed?
3.1.2. Are the key questions constructed in a way that the population, intervention, comparators, and effectiveness/safety outcomes being evaluated are clear?
3.1.3. Are there any other “clinically relevant” patient populations, interventions, comparators, and effectiveness/safety outcomes that should be considered and, if so, why?
3.1.4. Are there additional study designs that should be considered and, if so, why?
3.2 Providing additional references/citations for draft key questions: References and citations should not be submitted at this time, but during the dossier process.

4. Guidelines when commenting on draft reports

4.1. Considerations for the commenter: The public comment period for the draft report is your opportunity to give input on the review before it is finalized. Please consider the following elements when commenting on the draft report. (You need not specifically “answer” the following questions, they are provided only as a guide.)

4.2. Introduction: Is the background information adequate enough to help build context to convey the purpose of the review? Is there any background information that is incorrect or outdated?

4.3. Key Questions: Key questions have already been finalized and were previously available for public comment. Any comments regarding this issue will NOT be considered.

4.4. Methods:

4.4.1. Literature Search: Does the literature search strategy appear unbiased? Were any studies missed? (Please check inclusion criteria before suggesting studies)

4.4.2. Study Selection: Is the process clear and transparent? Do you believe studies were incorrectly excluded, based on the inclusion criteria, and if so, why?

4.4.3. Data Abstraction: Is the process clear and transparent? Have you identified errors? If so, please specify and cite your source.

4.4.4. Quality Assessment: Is the process clear and transparent? Using the quality assessment criteria and methods, do you believe studies were accurately rated? If not, which and why? Please cite your source if additional information is being provided to support quality criteria.

4.4.5. Synthesis: Are the methods clear and transparent? Do you feel a statistical method was inappropriately used? If so, which and why (please cite any sources to support your view)? Have you identified errors? If so, please specify, and cite your source. Are there specific statements that are unclear and out of place with the rest of the report? Have any major points been missed? If so, which and why (please cite any sources to support your view)?

4.5. Tables/Figures and Appendices: Are the form and arrangement of illustrations and tables satisfactory? Call attention to graphs and tables that are hard to read because they are crowded with too much information or to those that could save space if they were combined with other illustrations. Are there captions or symbols that may be better included in the legend? Do illustrations show what they purport to show?

4.6. Providing additional references/citations for draft reports: Please follow the following instructions when providing citations and reference materials.

4.6.1. When commenting on a draft report, check the report reference list and appendix of excluded studies to see if the study you are citing has been included/excluded.

4.6.2. Check the inclusion/exclusion criteria (see Key Questions section) of the review and assess whether your reference meets these criteria.

4.6.3. If the study has not been included in the draft report and you believe it meets the inclusion criteria, please provide a complete study reference citation in the appropriate box on the comment page and provide an electronic copy. An abstract alone is not sufficient. Electronic copies can be sent to sanborn@ohsu.edu. Note: any information submitted to the Center will become public.

4.6.3.1. Print materials of studies: If study information is not available electronically you are still encouraged to include the citation. If you intend to mail the study cited, please cite the study with the notice “PAPER COPY SUBMITTED”. Please submit a paper copy to: Erin Sanborn, Center for Evidence-based Policy, 3030 SW Moody Ave, Suite 250, Portland, OR 97201, Mailstop MDYCEBP
4.6.4. Type in complete reference citation into the appropriate text box and not with your comments.

Thank you for your input; public comments add value to our process and have the potential to improve the reports.