Expert Review Drug Profiles: Author Guidelines

http://informahealthcare.com/page/ExpertReviews

1. Introduction to Expert Review Drug Profiles

The audience for the Expert Review series consists of clinicians, research scientists, decision-makers and a range of professionals in the healthcare community. Authors should bear in mind the multidisciplinary status of the readership when writing the article.

Expert Review articles have been engineered specifically for the online environment. The structure is designed to draw the time-constrained reader directly to the information they require. Four features in particular contribute to the unique value of Expert Review articles:

- Expert commentary
- Five-year view
- Key issues
- Information resources

Aim:

The aim of a Drug Profile is to provide a concise review of the pharmacology, clinical efficacy and tolerability of a drug. Authors are encouraged to provide a critical appraisal of the most important and up-to-date information and provide their own viewpoint on the role of the drug in clinical practice.

Focus:

Authors should restrict their discussion to licensed indications and it is recommended that national/regional regulatory product guidelines are followed, particularly in terms of indications and dosage. When a drug is discussed outside of its approved license, readers should be made aware of this fact in the first instance.

For investigational drugs not yet licensed for any indication, the manuscript should make reference to this from the outset.

Timing:

Several factors contribute to the selection of drugs to be reviewed, including scientific need, emergence of new important clinical data, market launches/approval of new indications, and the requirement for an alternative appraisal of the literature. Thus timing is critical and it is important that the deadlines set by the Commissioning Editor are met. However, if you feel there is a need to delay publication, for instance to discuss new data presented at a scientific meeting or to coincide with the publication of primary literature, the Profiles Editor will be happy to accommodate such requests.

2. Drug Profile content

Every Drug Profile must contain:

Title

Should be concise but informative, including the drug and therapeutic indication. The title should contain no brand/trade names.

Authors' names and addresses

Including telephone number, fax number and email address and denoting an author for correspondence.

Summary
Not more than 150 words, this should not be an abstract but merely a scene-setting summary outlining the article scope and briefly putting it in context. The role of the summary is to draw in the interested casual browser. No references should be cited in the summary.

Keywords
A brief list of keywords to assist indexers in cross-referencing encompassing the therapeutic area, mechanism(s) of action, key compounds etc.

Introduction
Incorporating basic information on disease incidence and prevalence, unmet medical need and present treatment guidelines (highlighting regional variations where appropriate).

Body of review
Overview of the market:
• What are the unmet needs of currently available therapies?
• Which competitor compounds/classes of compounds are in the clinic/late development?
Introduction to the drug:
• Chemistry

• Pharmacodynamics
• Pharmacokinetics and metabolism
Clinical efficacy:
• (Phase I studies)
• Phase II studies
• Summary table of Phase I and II trial results
• Phase III studies
• Summary table of Phase III trial results
Post-marketing surveillance (if applicable):
• Safety and tolerability. Including a table summarizing safety outcomes in clinical trials, and also a table comparing the characteristics of the drug with its competitors.
Regulatory affairs:
• Include information on the status of the drug, i.e., where it is currently approved, in which countries it is approved and for what indications. Should cover EU, US and rest of the world where appropriate.

Conclusion
An analysis of the data presented in the review.

Expert commentary
This section affords authors the opportunity to go beyond the conclusion and provide their interpretation of the data presented in the article, discussing any improvements the drug has over currently available therapies and how likely physicians are to convert to treatment with the drug. In addition there is the opportunity to discuss the developments that are likely to be important in the future and the avenues of research likely to become exciting as further studies yield more detailed results (i.e. what are the prospects for combination therapies?).

Five-year view
Authors are challenged to include a speculative viewpoint on how the field will have evolved 5 years from the point at which the review was written.

Key issues
An executive summary of the authors' main points (bulleted) is very useful for time-constrained readers requiring a rapidly accessible overview.

Information resources
A brief summary to direct the reader to the most important further reading, related articles and relevant websites.

Annotated bibliography
Important references should be highlighted with a one/two star system and brief annotations should be given (see Section 3. for details).

3. House style

Word limit

Articles should be 5000-7000 words (not including tables, figures and references).

File formatting

Keep all formatting to a minimum. Do not assign 'styles' to headings, extracts or paragraphs. Make sure that the 'normal' style is used throughout the text. Turn off the automatic hyphenation feature.

Spacing and headings

Please use double line spacing throughout the manuscript. Headings, sub-headings and title paragraphs should be used to divide the text. Please use numbers to indicate a hierarchy of headings/sub-headings (i.e., 1., 1.1, 2., 2.1, 2.1.1, 2.1.2, etc.).

Abbreviations

Abbreviations should be defined on their first appearance, and in any table and figure footnotes. It is helpful if a separate list is provided of any abbreviations.

Spelling

US-preferred spelling will be used in the finished publication (e.g., leukemia, not leukaemia).

Companies

Companies are treated as single entities requiring a verb in the third person singular, e.g., GlaxoSmithKline is developing an AII antagonist. When referring to a lead compound (or compounds claimed in patents) for the first time, please ensure that the name of the relevant company is given in the text.

Drug brand names

Drug brand names should not appear in the Title or Summary. Ideally the brand name should only be used once in the main paper, in parentheses following the first mention of the generic name (please give both EU and US brand names where appropriate). The generic name should then be used thereafter. When referring to a lead compound (or compounds claimed in patents) for the first time, please ensure that the name of the relevant company is given in the text.

4. References

A maximum of 80 references is recommended for Drug Profiles. Authors should focus on recent papers, and papers older than 5 years should not be included except where there is an overriding purpose. Websites and patents may also be referenced as references but should be numbered after the references in a separate list. Unpublished data in the form of scientific abstracts or manuscripts in press are acceptable only if they add to or enhance the review.

NB. Papers or patents of particular interest should be identified using one or two asterisk symbols (* = of interest, ** = of considerable interest) and annotated with a brief sentence explaining why the reference is considered to be of interest.

References should be denoted numerically and in sequence in the text, using Arabic numerals placed in square brackets, i.e., [1,2]. List references in numerical order in the reference list.

Format and examples

References use plain, unformatted text, as in the following examples:

Journals:

1. Weissman P, Goldstein BJ, Rosenstock J, et al. Effects of rosiglitazone added to submaximal doses of metformin compared with dose escalation of metformin in type 2 diabetes: the EMPIRE Study. Curr Med Res Opin 2004;21:2029-35

Books:

2. Gottman J. Time Series Analysis. Cambridge: CUP, 1981

Working party reports and similar:

3. Clinical Disputes Forum Working Party. Pre-action protocol for the resolution of clinical disputes. London: Clinical Disputes Forum, 1998

Pre-publication articles assigned DOI numbers:

4. de Lau LM, Koudstaal PJ, Hofman A, Breteler MM. Subjective complaints precede Parkinson disease: the Rotterdam study. Arch Neurol 2006: published online 9 January 2006, doi:10.1001/archneur.63.3.noc50312

Internet articles and website information:
5. Suicidality in adults being treated with antidepressant medications. FDA Public Health Advisory. Washington, DC: FDA/Center for Drug Evaluation and Research, 2005. Available at: www.fda.gov/cder/drug/advisory/SSRI200507.htm [Last accessed 3 January 2006]
Patents:
6. Basf AG. Means and methods for preventing and treating caries. WO2006027265 (2006)
Use the following formats for patent numbers issued by the World, US and European patent offices, respectively: WO0113324; US6803189; EP1549318
Note, for citations with four or fewer authors/assignees, cite all names; for citations with more than four authors, cite three author names plus et al.
Full reference details must be provided in the bibliography (for example, for journal citations, author surnames and initials, article title, journal name, year, volume, page range). Failure to do so may lead to a delay in publication or a return of the paper by the Editor to the author.

5. Figures

Figures should be numbered consecutively according to the order in which they have been first cited in the text. Define in the legend all abbreviations that are used in the figure.
Figures should be provided in separate files to the text. It is unnecessary to incorporate the figures into the body of the manuscript.
Please ensure that scale bars are included where appropriate.
Please note: No figures are permitted in Editorials and Meeting Reports.

Color figure charge

Publication in color will be charged at $575 per paper.
This charge does not apply to the online (including PDF) version of articles, where all figures appear in color at no charge.

Chemical structures

If possible, please submit structures drawn in ISISDraw or Chemdraw format. However, chemical structures can be redrawn in-house. Please use the following conventions:
• Always indicate stereochemistry where necessary – use the wedge and hash bond convention for chiral centers and mark cis/trans bonds as such.
• Draw small peptides (up to five amino acids) in full; use amino acid abbreviations (Gly, Val, Leu, etc.) for larger peptides.
• Refer to each structure with a number in the text; submit a separate file (i.e., not pasted throughout the text) containing these numbered structures in the original chemical drawing package that you used.

Electronic figure files

Please submit any other illustrations/schemes in an editable electronic format such as Illustrator, PowerPoint, Excel or as postscripted/encapsulated postscripted (.ps/.eps) files.
Photos should be provided at a resolution of 600 dpi, or as high as possible

Copyright

If a figure has been published previously (even if you were the author), acknowledge the original source and submit written permission from the copyright holder to reproduce the material where necessary.
As the author of your manuscript, you are responsible for obtaining permissions to use material owned by others. Since the permission-seeking process can be remarkably time-consuming, it is wise to begin writing for permission as soon as possible.
Please send us photocopies of letters or forms granting you permission for the use of copyrighted material so that we can see that any special requirements with regard to wording and placement of credits are fulfilled. Keep the originals for your files. If payment is required for use of the figure, this should be covered by the author.

6. Tables/Boxes

Tables/Boxes should be numbered consecutively according to the order in which they have been first cited in the text. Define in the legend all abbreviations that are used in the table/box.
Tables/boxes to appear in the article should fit onto one A4 page. Any table/box larger than one A4 page will be

included as an online supplementary file.
Please note: No tables or boxes are permitted in Editorials and Meeting Reports.

Electronic files

Tables/Boxes should be provided in separate files to the text, preferably in either Word or Excel format. It is unnecessary to incorporate the tables/boxes into the body of the manuscript.

Copyright

If a table or box has been published previously (even if you were the author), acknowledge the original source and submit written permission from the copyright holder to reproduce the material where necessary.
As the author of your manuscript, you are responsible for obtaining permissions to use material owned by others. Since the permission-seeking process can be remarkably time-consuming, it is wise to begin writing for permission as soon as possible.
Please send us photocopies of letters or forms granting you permission for the use of copyrighted material so that we can see that any special requirements with regard to wording and placement of credits are fulfilled. Keep the originals for your files. If payment is required for use of the table/box, this should be covered by the author.

7. Submission and deadlines

Please ensure that manuscripts are submitted on or before the deadline issued by the Profiles Editor. If you are unable to meet the deadline set, please discuss with the Profiles Editor to determine a new submission schedule.

Peer review

All Drug Profiles are subject to rigorous peer-review by selected members of the scientific community with extensive knowledge of the drug under review. This typically takes 3–4 weeks from manuscript submission, however, we do have rapid publication options (listed below). All feedback from the reviewers, together with our editors' recommendations, will be returned to you for consideration and a further 2 weeks is then allowed for any revisions to be made. Upon acceptance of the revised draft, the final version will then be typeset and edited in-house. A page proof is sent to the author for final approval before the journal is sent to press. Further information is available in the Journal Polices section below.

Additional feedback

In addition to the peer-review process, with the author's consent the company manufacturing the drug will also be given the opportunity to provide feedback on the review in terms of inconsistencies, nomenclature, missing data, etc. The company will not be asked to comment on the interpretation of the data or opinions presented (unless there is a scientific need to do so).

Rapid Publication

Publication in Expert Reviews is driven entirely by editorial considerations and independent authoritative peer review. As part of the journal's responsive approach to the publication of clinical evidence, we offer two prioritised modes of rapid publication and a third non-prioritised mode:

- FastTrack: This offers the most highly prioritised service, with a submission to online publication timeline of 5–7 weeks (subject to 1–2 week author revision following initial peer-review and prompt turnaround of proofs). There is a publication support fee for this, based on a charge of $850/€625/£550 per published page. This charge supports the ultra-swift processing of material and 20 downloads of the article via e-access tokens.
- Rapid Track: This prioritised service offers submission to online publication in 10–12 weeks and is subject to a publication support fee of $400/€300/£260 per page; 10 downloads of the article are also provided.
- StandardTrack: This non-prioritised standard service provides submission to online publication in up to 20 weeks; there are no publication support fees charged for this mode.

Expert Reviews welcomes contact with the Editorial Offices preceding formal submission and particularly encourages prior contact for FastTrack submissions where a particular publication deadline is desired.

8. Journal policies

Expert Reviews titles endorse the Uniform Requirements for Manuscripts Submitted to Biomedical Journals, issued by the International Committee for Medical Journal Editors, and Code of Conduct for Editors of Biomedical Journals, produced by the Committee on Publication Ethics. This information is also available at http://informahealthcare.com/page/ExpertReviews.

Manuscript submission & processing

Expert Reviews titles publish solicited and unsolicited reviews. Receipt of all manuscripts will be acknowledged within 1 week and authors will be notified as to whether the article is to progress to external review. Initial screening of articles by internal editorial staff will assess the topicality and importance of the subject, the clarity of presentation, and relevance to the audience of the journal in question.

Please submit your article online at http://mc.manuscriptcentral.com/expertreviews

External peer review

Through a rigorous peer review process, Expert Reviews titles aim to ensure that reviews are unbiased, scientifically accurate and clinically relevant. All articles are peer reviewed by three or more members of the International Advisory Board or other specialists selected on the basis of experience and expertise. Review is performed on a double-blind basis – the identities of peer reviewers and authors are kept confidential. Peer reviewers must disclose potential conflicts of interests that may affect their ability to provide an unbiased appraisal (see Conflict of Interest Policy below). Peer reviewers complete a referee report form, to provide general comments to the editor and both general and specific comments to the author(s).

Revision

Most manuscripts require some degree of revision prior to acceptance. Authors should provide two copies of the revised manuscript – one of which should be highlighted to show where changes have been made. Detailed responses to reviewers' comments, in a covering letter/email, are also
required. Review manuscripts may be accepted at this point or may be subject to further peer review. The final decision on acceptability for publication lies with the journal editor.

Post-acceptance

Accepted review manuscripts are edited and authors will receive proofs of their article for approval and sign off and will be asked to sign a transfer of copyright agreement.

Author disclosure & conflict of interest policy

Authors must state explicitly whether potential conflicts do or do not exist (e.g. personal or financial relationships that could influence their actions) and any such potential conflict of interest (including sources of funding) should be summarized in a separate section of the published review. Authors must disclose whether they have received writing assistance and identify the sources of funding for such assistance. Authors declaring no conflict of interest are required to publish a statement to that effect within the article.

Authors must certify that all affiliations with or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in their manuscript have been disclosed. Please note that examples of financial involvement include: employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending and royalties. This is list is not exclusive of other forms of financial involvement. Details of relevant conflicts of interests (or the lack of) must be declared in the 'Disclosure' section of the manuscript for all listed authors.

External peer reviewers must disclose any conflicts of interest that could bias their opinions of the manuscript, and they should disqualify themselves from reviewing specific manuscripts if they believe it appropriate. Should any such conflict of interest be declared, the journal editor will judge whether the reviewer's comments should be recognized or will interpret the reviewer's comments in the context of any such declaration.

Ethical conduct of research

For any original research submissions containing data relating to human or animal experimental investigations, appropriate institutional review board approval is required and should be described within the article. For those investigators who do not have formal ethics review committees, the principles outlined in the Declaration of Helsinki should be followed. For investigations involving human subjects, authors should explain how informed consent was obtained from the participants involved.

Patients' rights to privacy

Patients have a right to privacy that should not be infringed without informed consent. Identifying information should not be included unless the information is essential for scientific purposes and the patient (or parent or legal guardian) gives written informed consent for publication. Informed consent for this purpose requires that the patient be shown the manuscript to be published. When informed consent has been obtained it should be indicated in the manuscript.

In attempting to maintain patient anonymity, identifying details should be omitted where they are not essential.

However, patient data should never be amended or falsified. Informed consent should be obtained whenever there is any doubt that anonymity can be assured.

Use of personal communications & unpublished data

Where an individual is identified within a review as a source of information in a personal communication or as a source for unpublished data, authors should include a signed statement of permission from the individual(s) concerned and specify the date of communication.

Permissions for reproduced or adapted material

Authors must acknowledge the origin of all text, figures, tables or other information that has been adapted or reproduced from other publications. Authors must provide a copy of the original source documents and should submit permission from the authors of the original work and the original publishers for unlimited use in all markets and media (that includes both electronic and print use in any language).

Duplicate publication/submission & plagiarism

All manuscripts submitted to Expert Reviews titles are considered for publication on the understanding that they have not been published previously elsewhere or are under consideration for publication elsewhere. The journal may, however, consider republication of a paper previously published in a language other than English, subject to prominent disclosure of the original source and with any necessary permission. Authors will be asked to certify that the manuscript represents valid work and that neither this manuscript nor one with substantially similar content under their authorship has been published or is being considered for publication elsewhere, except as described in an attachment, and copies of closely related manuscripts are provided.

All submitted articles will be evaluated using plagiarism detection software, which compares the submitted manuscript with full text articles from all major journals databases and the internet.

The use of published or unpublished ideas, words or other intellectual property derived from other sources without attribution or permission, and representation of such as those of the author(s) is regarded as scientific misconduct and will be addressed as such.

Misconduct

If misconduct by authors or reviewers is suspected, either pre- or post-publication, action will be taken. An explanation will be sought from the party or parties considered to be involved. If the response is unsatisfactory, then an appropriate authority will be asked to investigate fully. Expert Reviews will make all reasonable attempts to obtain a resolution in any such eventuality and correct the record or archive as necessary.