# Expert Opinion on Emerging Drugs:
# Author Guidelines

## 1. Overview

*Expert Opinion on Emerging Drugs* was devised with the intention of providing an expert evaluation of the most important emerging drug technologies. These are assessed in terms of their potential impact on the current management of specific diseases.

Many sources of information on compounds in development are available to R&D decision makers, but none of these provides an accessible and independent assessment of the commercial and technical viability of the most promising areas of drug research. *Expert Opinion on Emerging Drug*s seeks to fulfil this function by commissioning recognised opinion leaders to write focused appraisals of areas of innovative medical research, which can be readily understood by a scientifically-literate, but not necessarily expert, audience.

Each issue contains chapters on a variety of subjects, each of them profiled according to the standard format outlined below. The chapters are expected to be able to stand alone in terms of their coverage of each individual area, but their uniformity, in terms of the sections covered in each of the chapters, is designed to facilitate comparative evaluation.

**1.1 Scope:** The ideal review article will provide both a critical evaluation and the author's opinion of the quality and novelty of the information disclosed.

**1.2 Audience:** *Expert Opinion on Emerging Drugs* is essential reading for pharmaceutical and academic scientists, research planners, product managers, clinical opinion leaders and healthcare planners.

**1.3 Peer-review:** All articles are subject to double-blind, independent peer-review. When all comments have been submitted to the Editorial Office, they will be collated and forwarded to the author, along with any Editorial recommendations. Comments remain confidential and are shared only with the corresponding author or submitting party. For a detailed description of the journal's peer review process, authors are referred to the journal's website.

**1.4 Length:** 5000 - 7000 words (not including tables, figures and references).

## 2. Manuscript content

Every article must contain:

### 2.1 Title

All article types should have a concise, informative title that contains no brand names.

### 2.2 Authors' names and addresses

Including address, academic qualifications and job titles of all authors, as well as telephone number, fax number and email address of the author for correspondence on a **separate cover sheet** as the peer reviewers will be blinded to the authors' identity. Please note that only the address of the first author of the article will appear on Medline/PubMed, not necessarily the corresponding author.

### 2.3 Abstract (~200 words)

The aim of the abstract is to draw in the interested reader, so the clearer and more insightful your abstract is the more interest the manuscript will attract. For full-length Review articles, the following structure is requested to make the most of your abstract:

***Importance of the field*** Authors are required to provide a statement on the significance of the topic under discussion and reason for this review

***Areas covered in this review*** Authors are required to describe the research discussed and the literature search undertaken, including years covered.

***What the reader will gain*** Authors are required to provide a statement on what learning will be undertaken by reading the paper, e.g., what knowledge gaps will be filled, what insight will be gained

***Take home message*** Authors are required to provide a statement on key message of the paper

For other, briefer article types, such as Editorials and Perspectives, the above sections are not required, but the abstract must describe the nature and objective of the paper.
References must not be included in the abstract. You will be required to remove them and renumber your references if they are included in the abstract.

### 2.4 Keywords

A brief list of keywords, in alphabetical order, is required to assist indexers in cross-referencing. The keywords will encompass the therapeutic area, mechanism(s) of action, key compounds and so on.

### 2.5 Body of the article

- **Background**

A concise introduction to the subject under review, couched in lay terms. The molecular targets that will be modified by the proposed research should be introduced, although further explanation should await the section, *Scientific rationale*. Information on the prevalence of the disease and the social and financial implications of treatment should be included.

- **Medical need**

This section should focus on the need for alternative/improved remedies for specific indications. For example, the limited palliative relief provided to arthritis patients by NSAIDs and the frequent impracticalities of surgery in a typically ageing population, highlight the need for genuine disease modifying therapy.

- **Existing treatment**

This may be included as either a subsection of *Medical need*, or as a seperate section, discussing the short-comings of currently-available therapy and where there are significant problems, e.g., side-effects, dosing regimens, lack of efficacy, etc.

- **Market review**

A logical sequel to the above sections and an introduction to the next is a quantification of the current market size broken down in terms of territories, for the particular indication/drug category being discussed (see sample chapter provided). An estimation of the annual growth should also be included. These data should be tabulated, both for emphasis and brevity; comments should be limited to issues likely to affect the market acceptance of, or readiness for, particular therapeutic proposals. It is important to authenticate the source of the information quoted. If possible, a table of currently available compounds (or drug types), together with their market share should be included. The Editor may be able to obtain some data on a case by case basis.

- **Current research goals**

This section should summarise briefly the aims of current research into the therapeutic area/drug class in question, as a prelude to the next section.

- **Scientific rationale**

Clear communication skills must be exercised to describe complex scientific concepts in such a manner that the basic principles of the specific disease target can be appreciated and the reader made able to satisfy himself/herself that the proposal is scientifically tenable. Equally, the scientific hypothesis can often form the basis for the prediction or anticipation of adverse events to which attention should be drawn. Serious consideration should be given to the inclusion of an illustration as an aid to understanding.

- **Competitive environment**

This section should review specific compounds with claims for activity in the therapeutic target involved. The products selected would normally be derived from the literature or Pharmaprojects, although other substantiated sources may be accessed. The aim of this section is to demonstrate clearly and succinctly what compounds are in development for a given indication, who they are being developed by and what stage they have reached in development. Authors should provide their comments in the form of evaluated/considered opinions on the prospects for this particular drug. Any additional data should be added in here, e.g., potency, side-effects, likely success, etc.

*Competitive environment table*

Each review should include a table following the template provided. Authors will be provided with information from Pharmaprojects in order to complete this section.

**Template Competitive Environment Table**

| Compound | Company | Structure | Indication | Stage of development | Mechanism of action |
|---|---|---|---|---|---|
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- **Potential development issues**

These may arise as a consequence of the reviews above (e.g., class-specific, pharmacologically-linked adverse events) or be consequential of particular chemical structures. Alternatively, social issues and those of high public interest (e.g., AIDS) or comparatively elusive patient populations may influence the attractiveness of a given area. Existing orphan drug studies should be indicated where appropriate.

### 2.6 Conclusion

The conclusion for all articles should contain an analysis/summary of the data presented in the article. Please note that this section is meant to be distinct from, and appear before the 'Expert opinion' section.

### 2.7 Expert opinion

To distinguish the articles published in the *Expert Opinion* series, authors **must** provide an additional section entitled 'Expert opinion'. This section affords authors the opportunity to provide their interpretation of the data presented in the article and 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. Authors should answer the following:

- What are the key findings and weaknesses in the research done in this field so far?
- What potential does this research hold? What is the ultimate goal in this field?
- What research or knowledge is needed to achieve this goal and what is the biggest challenge in this goal being achieved?
- Where do you see the field going in the coming years? What is going to happen?
- Which drugs discussed in this paper are likely to hold the most promise?
- Is there any particular area of the research you are finding of interest at present?

Please note that 'opinions' are encouraged in the Expert opinion section, and as such, referees are asked to keep this in mind when peer-reviewing the manuscript.

### 2.8 Annotated bibliography

Important references should be highlighted with a one/two star system and brief annotations should be given (see Section 5 of these guidelines for examples and for a more detailed description of our referencing style).

## 3. Pharmaprojects

Pharmaprojects is a weekly-updated, enterprise-wide competitor intelligence and R&D monitoring service, providing validated, integrated and evaluated information on all aspects of drug development, from first patent application to launch or discontinuation. Pharmaprojects is a product of the same publishers of the Expert Opinon journals, and authors are encouraged to request information from this database to be cited in their Expert Opinion papers. However, a company subscription is required, which is why we do drug searches for our authors. This service should be used to complete the 'Competitive environment' section. Please complete the form found at the end of these guidelines and return to the Commissioning Editor. This may also be used to receive information on patents.

## 4. House style

### 4.1 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.

### 4.2 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 (Arabic numerals) to indicate a hierarchy of headings/sub-headings (i.e., 1., 1.1, 2., 2.1, 2.1.1, 2.1.2 and so on).

### 4.3 Abbreviations and units

Abbreviations should be defined on their first appearance both in the abstract and in the text; commonly used abbreviations need not be defined. Authors are encouraged to submit a list of abbreviations used to the Editorial Office alongside the manuscript. Use SI units or quote SI equivalents where possible. To indicate atom positions in a molecule, use the convention C-1, C-2 and so on.

### 4.4 Spelling

Manuscripts may be submitted in either US or UK English and will be published using the version of English used in the manuscript submitted to the Editor.

### 4.5 Companies and drug brand names

- Companies are treated as single entities requiring a verb in the third person singular (e.g., GSK is developing an AII antagonist).
- Drug brand names should not appear in paper titles. In the body of the review, the generic name should be used in preference to brand names. Drug brand names are to be used only if absolutely necessary. In such a case, when referring to a lead compound (or compounds claimed in patents) for the first time, please ensure that the ® or ™ symbols are used as required, and that the name of the relevant company is also stated. Generic names always take a lower case first letter unless they are beginning a new sentence.

## 5. References

Articles should principally review recent primary literature and scientific meeting reports, rather than patents, although relevant patent information may be included where appropriate.

Websites of interest may also be referenced. Occasional 'historic' papers may be cited.
Ensure that all key work relevant to the topic under discussion is cited in the text and listed in the bibliography. Reference to unpublished data should be kept to a minimum and authors must obtain a signed letter of permission from cited persons to use unpublished results or personal communications in the manuscript.

### 5.1 Numbering

References MUST be numbered consecutively, using Arabic numerals in square brackets, in the order in which they are first mentioned in the text. The reference list should appear in the *same sequence* as the numbers in the text.

### 5.2 Annotations

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.

### 5.3 Bibliography

References can be formatted using EndNote or Reference Manager according to the style of *Current Medical Research and Opinion*. 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.

## 6. Tables

Number tables consecutively in the order of their first citation in the text. Place explanatory matter in the footnotes, not in the header. Define in the footnotes all abbreviations that are used in the table. Be sure each table is cited in the text. If you are using data from another published or unpublished source, please obtain permission and acknowledge the source(s).

## 7. Illustrations

Do include illustrations (figures/diagrams/structures) as appropriate. Please ensure that the following recommendations are adhered to as closely as possible:

- Provide electronic copies if possible; otherwise, please ensure that camera-ready copy is of the highest resolution available.
- Please submit figures as eps, illustrator, jpeg, ISISdraw or ChemDraw format.
- Figures should employ CMYK rather than RGB colour scheme.
- Small figures should be 300 dpi and large figures should be 72 dpi.
- Figures and structures should be in separate files to the text. It is unnecessary to incorporate the figures into the body of the manuscript. If there are several figures, please submit these individually, rather than as one file (preferably the original source files). We cannot improve resolution beyond that of the file submitted.
- If these formats are not possible, figures can be submitted in PowerPoint or Word as a last resort.
- 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.
- If a figure has been previously published, acknowledge the original source and please submit written permission from the copyright holder to reproduce the material.

**Publication in colour costs £100/$150/€120 per colour figure.**

### 7.1 Chemical structures

Please submit structures drawn in ISISDraw or Chemdraw and ensure that you submit these in their original, editable format. Also, use the following conventions:

- Always indicate stereochemistry where necessary – use the wedge and hash bond convention for chiral centres and mark *cis*/*trans* bonds as such.
- Draw small peptides (up to five amino acids) in full; use amino acid abbreviations (Gly, Val, Leu and so on) for larger peptides.
- Refer to each structure with a number in the text and submit a separate file (i.e., not pasted throughout the text) containing these numbered structures in the original chemical drawing package that you used.
- Where structures do not appear as part of a figure, number each structure (using Arabic numerals only) and cite the compound number in the body of the article. Note that structures within figures can also be cited in this way.

## 8. Copyright

As the author of your manuscript, you are responsible for obtaining permissions to use material owned by others. As the permission-seeking process can be remarkably time-consuming, it is wise to begin writing for permission as soon as possible. A template permission letter is available on request. 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. **You will be asked to transfer copyright to Informa UK Ltd following acceptance for publication. If there are any problems with this, this should be raised with the Editor as soon as possible.**

### 8.1 NIH/Wellcome-funded research

For NIH/Wellcome-funded manuscripts Informa Pharmaceutical Science will deliver to PMC/UKPMC the final peer-reviewed manuscript, which was accepted for publication and that reflects any author-agreed changes made in response to the peer review. We will also authorize the author manuscript's public access posting 12 months (NIH) or 6 months (Wellcome Trust) after final publication. Following the deposit, authors will receive further communications from the NIH Manuscript Submission System/UK Manuscript Submission System with respect to the submission. It is the author's responsibility to make the Editor aware of this funding as early as possible.

## 9. Declaration of interest

It is the responsibility of authors to disclose any affiliation with any organisation with a financial interest, direct or indirect, in the subject matter or materials discussed in the manuscript (such as consultancies, employment, expert testimony, honoraria, speakers bureaus, retainers, stock options or ownership) that may affect the conduct or reporting of the work submitted. If uncertain as to what might be considered a potential conflict of interest, authors should err on the side of full disclosure. Information about potential conflict of interest may be made available to reviewers and may be published with the manuscript at the discretion of the Editors. The declaration of interest statement must be returned to the Editor upon submission (see end of this document).

**For a detailed description of all the journal's editorial policies, including plagiarism, authorship, patient privacy, and redundant publication, authors are referred to the editorial policy document on the journal's website**.

## 10. Submission

Please submit manuscripts in Microsoft Word (double spaced, Times New Roman, 12 pt) using the Manuscript Central online submission system (http://mc.manuscriptcentral.com/eomd). As the peer reviewers will be blinded to the identity of the authors, contributors MUST provide a copy of the manuscript containing no author names or affiliations. These details should be provided on a separate cover sheet. Pages must be numbered.

## 11. Deadlines and what happens after you submit

- Please ensure that manuscripts are submitted on or before the deadline issued by the Editors.
- Please provide an outline of your article 1 month prior to the submission deadline. This will enable us to find suitable referees.
- Once the manuscript has been received in-house, it will be peer-reviewed (this usually takes ~ 3 weeks). A further 2 weeks is then allowed for any revisions (suggested by the Referees/Editor) to be made.
- The final version is then typeset and edited. Page proofs are sent to the author for final approval before the journal is printed.

**Note:** If a manuscript requires company authorisation before submission, please remember to take this into account when working towards these deadlines.

## 12. Contact details

If you have any queries with regard to submission or publication, or would like to find out more about other *Expert Opinion* titles, please contact us at the address below:

**Commissioning Editor:**

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**E-mail**: misty.bond@informa.com;
**Website:** http://www.informahealthcare.com/emd

## 13. Submission Checklist

Before submission of your manuscript, please ensure that the following criteria are met:

**General**

- Word count: 5000 – 7000 (not including figures, tables and references)
- Number of figures: no more than 5
- Number of tables: no more than 5
- Submit a list of abbreviations used in the manuscript
- Submit confirmation of figure permissions with submission
- Disclosure statement MUST be submitted WITH manuscript
- Submit manuscript online at http://mc.manuscriptcentral.com/eomd
  Include: i) covering letter, ii) completed Disclosure Form, iii) main document (containing no author details) (in MS Word, double spaced, Times New Roman, 12 pt) and iv) any separately attached image files.
- Pages must be numbered
- Author details must be provided on separate cover sheet
- Paper will be published in UK or US English depending on how it is submitted
- All figures and tables cited in the text are supplied. No figures or tables appear without being cited in the text
- Tables are in cellular format, appearing at the end of the manuscript (following the references)
- All figures are supplied as editable, separate files with the legends appearing on a fresh page at the end of the manuscript.

**Sections**

- Abstract
- Keywords
- Background
- Medical need
- Existing treatment
- Market review – this is may be omitted if you are unable to obtain the relevant data, but please ask the Editor, as we may be able to obtain data for you
- Current research goals
- Scientific rationale
- Competitive environment – please submit signed search form found in author guidelines to complete this section
- Expert Opinion

**References**

- Number of references: no more than 100
- Reference annotations present
- Journal reference style is adhered to as closely as possible
- References are listed numerically, and not in alphabetical order
- Abstract/titles do not contain references
- Check references match the citations in the text to avoid later problems

**Please be aware that failure to meet the above criteria may delay the publication of your manuscript.**

## Pharmaprojects search form

Fax: For the attention of Misty Bond +44 (0)20 7017 7667

**Search requested by:**

Name .....

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Article in preparation .....

Copy deadline .....

| Please supply details of drugs on the following topics: | | | |
|---|---|---|---|
| KEYWORDS | SYNONYMS | ABBREV. | CONTEXT |
| e.g., serotonin | 5-hydroxytryptamine | 5-HT | anxiety/anxiolytic |
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| Compounds of special interest: | | | |
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I hereby declare that the information supplied to me by *Expert Opinion* will be used solely for the preparation of the commissioned review for *Expert Opinion on Emerging Drugs* and not for any other publication.

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**Some or all of the information below may be published at the discretion of the Editor as a *Declaration of Interest* statement in the Acknowledgment section of the manuscript. Please note that this section must be present before we initiate peer review.**

**1.** The manuscript submitted represents original work and has not been previously published or simultaneously submitted elsewhere for publication.
*Yes to all above* ____
*No, because*……..……..
……

**2.** The manuscript has been read and approved by all authors.
*Yes* ____
*No, because*……..……
……

**3**. All conditions as stated by the International Committee of Medical Journal Editors (ICMJE; http://www.icmje.org) have been met.
*Yes* ____
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**4**. For clinical studies, the body providing explicit ethical approval of the work reported has been stated in the manuscript.
*Yes* ____
*No, because*……..……
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**5**. For clinical trials, please provide trial registration information and a trial registration number for the study (where available):
……

**6**. How has your paper been sponsored/funded? Please name all academic bodies, and/or pharmaceutical (or other) companies that have supported this work, in whole or in part.

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**Authorship/disclosure/'contributorship'**

**7.1** If any employees of the sponsors/other contributors meet the criteria for authorship (as per ICMJE guidelines – see first bullet point under section IIA. 1 of the Uniform Requirements – http://www.icmje.org/), then, these individuals should be added as authors on the manuscript.

**7.2** If they do not meet authorship criteria, but the sponsor/other contributor(s) had a role in the preparation of the manuscript, this should be explained. Did the sponsors have a role in article preparation – study design/data analysis/statistical input/review of drafts/writing of the article/identification of papers for inclusion/any other form of input?

Describe here: ……

……

**8.** A statement of financial, commercial or other relationships of a declarable nature relevant to the manuscript being submitted, (i.e., associations/relationships with the sponsors or any other associations which might lead to a potential conflict of interest), must be provided.

Please include the following information for each individual coauthor:
**(A)** Disclosure of sources of support in the form of sponsorship, grants, materials, etc.
**(B)** Declaration of interest, including grants, fellowships, or commercial assistance or financial sponsorship received; or of any affiliation, organization or entity which is relevant.

Lead author: Name: ……
Disclosure: ……
……
Corresponding author: Name: ……
Disclosure: ……
……
Coauthor: Name: ……
Disclosure: ……
……
Coauthor: Name: ……
Disclosure: ……
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(Use additional pages if this space is insufficient.)

**9.1** Acknowledge any further contributions to this paper, such as data analysis, statistical analysis, data collection, data management or any other assistance.
**9.2** We recognise the role of the professional medical writer and medical communication agencies. In case any writing/editorial assistance was taken for the preparation of this article, then, include also the agency and the writer(s)/person(s) to be acknowledged.

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Nature of contribution: ……

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I confirm that I, all coauthors, medical writers and other contributors to the manuscript have provided full disclosure regarding any relevant relationships, financial and otherwise.

…… ……

***Corresponding author signature*** ***Date***

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