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# UKDILAS Clinical Advisory Database

# Writing Guide

1. **Introduction**
   1. UKDILAS monographs are written for the Drugs in Lactation section of the SPS website, which is the main user-facing output of UKMI’s specialist advisory service on drugs in lactation. A parallel archive version for internal backup and sourcing other UKDILAS outputs is maintained for internal use only.
   2. The monographs are written to be applicable to a wide range of users, including clinicians, nurses, midwives, health visitors, pharmacists, breastfeeding advisers and organisations. It is not specifically written for the general public, especially mothers who are breastfeeding their infants – mothers using the information are advised to contact a healthcare professional or expert adviser for clarification.
   3. The database uses the British National Formulary (BNF) only as a broad framework for structuring entries into therapeutic/pharmacological categories. However, to achieve maximum comprehensiveness for a UK and international audience, sections may contain drugs that are not available in the UK. It will also contain sections which do not appear in the BNF but which are encountered in breastfeeding mothers, e.g. contrast media, sweetening agents etc. *The long-term use of the BNF structure will be re-assessed in due course.*
   4. The purpose of this Writing Guide is to define the processes to be followed by those designated within Trent and West Midlands MI Centres in the production and maintenance of entries into UKDILAS monographs for subsequent incorporation onto SPS and the internal UKDILAS archive.
   5. Database entries should be evidence based, concise, and of high quality. This Guide covers all the processes in writing, updating, checking and managing entries into the database.
2. **Writing new sections**

These will be minimal as the core database is completed. The principles, however, will apply to entering new drugs and undertaking revisions.

* 1. **Evidence summary**
     + Evidence summary to be collated into current Word template (see [Appendix 1](#App1)) for a minimum of UKMi Q&A, UKDILAS Clinical Summary, Lactmed and Hale. If the latter two are in conflict, missing or inadequate include summary from Briggs. If still inadequate include data from other sources, possibly SPC, Martindale, Reprotox, past queries (with care), other internet sources etc. Record sources if ‘other’ used.
     + The evidence summary will normally be:
       1. UKMi Q&A or UKDILASD Summary: Copy of conclusions/recommendations.
       2. Lactmed: copy of monograph summary, edited and/or supplemented where necessary.
       3. Hale: edited summary of monograph, especially conclusions/recommendations. Also include Hale’s classification (e.g. ‘Cat L2’) and summary of relevant pharmacokinetic/ dynamic data, e.g. t1/2, MW, M/S, PB, oral.
       4. Briggs: normally only include conclusion and recommendation/classification
     + Check content of references when considered necessary. Note any references cited by the above sources but missing from the UKDILAS reference database and inform PG.
  2. **Data table**
     + Complete all sections of the data table from the evidence summaries.
       1. **Drug name:** use the convention in [Appendix 2](#App2) to distinguish different qualifiers, e.g. indication, synonym, route etc.
       2. Put qualifiers on a new line (under the drug name) by adding **<br>** after the drug name to force a line break, e.g. **Estradiol****<br><i>**as a contraceptive **</i>** *(Archive version)*
       3. NB: ‘Unlicensed’ or ‘Not available in UK’ will be added as comments, not qualifiers, if appropriate.
     + **Recommendation:** cut and paste appropriate entry (Yes, Caution, No) from the options at the bottom of the table.
     + **Comments:** 
       1. Select comments from the Standard Comments list ([Appendix 3](#App3)).   
          *Note: Standard Comments are intended as a guide to reduce variability and increase consistency of wording. They are not intended to be inflexible.*
       2. Use the minimum number of comments to clarify the recommendation.
       3. Avoid using comments because they automatically apply – be selective.
       4. Combine standard comments where it makes related or dependant comments clearer.
       5. Modify standard comments, or write a new, ad hoc comment, when standard comments are inadequate, ambiguous or better expressed with revised wording.
       6. Freetext or combined standard statements should be highlighted yellow in the template. Comments should NOT be ended with a full stop (which will be added automatically on online entry)
       7. Follow the standard priority order of comments:
* Synonyms, licence status *(rarely used)*
* Level of evidence (mandatory)
* Pharmacokinetic/quantitative related comments
* Adverse effects (if reported)
* Monitoring
* Use in neonates
  + - **Alternatives**: choose an alternative(s) for drugs with a Caution or No recommendation relevant to the indication. This would normally be alternative drugs in the same section, but can be drugs from other relevant sections. It can also be a non-pharmacological alternative if appropriate. If no safer alternative enter a hyphen.   
      ‘Yes’ drugs will not normally have an alternative stated unless there is a condition or qualification to the Yes status.
    - **Evidence sources:** Use the most appropriate available source that includes the references and conclusion that most closely supports the recommendation and comments made.
      1. Use Q&A or UKDILAS
      2. If not, use Bibliography which hyperlinks to an explanatory page of the use of LactMed, Hale, Briggs and other sources.  
         *Note: This entry is intended only to refer to the evidence used to make the recommendation, It is not necessarily to agree with the conclusion of the evidence source.*
  1. **Section summary**
     + Write a section/group summary including overall group recommendations and evidence themes consistent for the whole section. This can include an introduction to the use of drugs in the section.
     + The summary should include as many points as considered necessary to give clarity to the user and to reduce duplication within individual entries. It can also be used to emphasise a critical point in an individual entry.
     + Paragraphs in a section summary are separated by a line break **<br>** at the end of the paragraph text,  
       e.g. Paragraph 1 text.**<br>**Paragraph 2 text.
  2. Section summaries can include information on indications, adverse effects, background, evidence themes, hyperlinks to guidelines etc.
  3. Section summaries are combined into Group Summaries for SPS Articles in line with UKDILAS Database Structure (see [www.midlandsmedicines.nhs.uk/filestore/ukdilas\_files/UKDILAS\_Structure\_Version2\_current.xlsx](http://www.midlandsmedicines.nhs.uk/filestore/ukdilas_files/UKDILAS_Structure_Version2_current.xlsx)

1. **Writing new drugs/indications**
   1. New drugs are identified on an ongoing basis through scanning e-MIMs, Pharmaceutical Journal, NICE Medicines Awareness Daily, PharmaTimes Daily, e-MC and BNF, supplemented from MI intelligence sources. The evidence for the new drug is assessed from normal sources and an appropriate entry made in the appropriate section template.
   2. The amended section is then sent for checking (SF) after which an appropriate entry is made on the online and archive database.
   3. An appropriate entry in the ‘Change’ table, and a version control amendment (see #7) are made.
   4. File naming will follow the normal style (see #9) but with a new secondary version number (e.g. 2.0 becomes 2.1)
2. **Multiple entries**
   1. Drugs may have more than one entry in the database. These can occur when:
      * The drug appears in more than one therapeutic section. The entry may be the same in multiple entries or it may be different if the indication, dose or route changes the risk level.
      * The drug has more than one route, formulation or dose within a therapeutic section for which the risk level if different.
   2. In all cases, add an indication, formulation, dose or route qualifier to the drug name, as appropriate, to differentiate between entries when searching ([Appendix 2](#App2)).
3. **Discontinued drugs**
   1. Discontinued drugs are identified on an ongoing basis through scanning the sources listed in 3.1.
   2. A new comment is added to the appropriate section template: “<Drug> discontinued in the UK <month, year>. If not already stated, an alternative drug is specified.
   3. No check on the entry is required.
   4. An appropriate entry in the ‘Change’ table, and a version control amendment (see #7). are made
   5. File naming will follow the normal style (see #9) but with a new secondary version number (e.g. 2.0 becomes 2.1)
   6. The entry will remain in the database in the appropriate section for non-UK users.
4. **Routine 3-yearly revision**
   1. All sections will be reviewed every 3 years, even if amendments have been made to individual entries within the last 3 years. The date of section revision is detailed in the ‘WebsiteProgressChecker’ spreadsheet.
   2. Sections will, where possible, be revised by the original writer.
   3. The process for evidence collection and assessment is the same as for writing a new section (see #2). Where a previous version (early v1.0 sections) did not use the current template, data in the original version will be transferred onto the new template, including completion of the evidence table.
   4. Changes will also be made to ensure consistency with other database entries for the same drug and for compliance with the drug name qualifiers policy [(Appendix 2)](#App2)
   5. Changes to any of the entries from the previous version will be entered with track changes. Any comments required to justify the changes will be added using ‘<Review<>New comment>.
   6. File naming will follow the normal style (see #9) but with a new primary version number (e.g. 1.0 becomes 2.0).
   7. The process for checking, data web upload and web checking will follow that for a new section.
5. **Ad hoc revisions**
   1. Ad hoc revisions, i.e. those between the 3-yearly whole section revisions, will be made for:
      * 1. New drugs (see #3)
        2. New indications (i.e. drug appears in additional BNF chapter/database section) (see #3)
        3. Discontinued drugs (see #5)
        4. Addition of indication, synonym or route for existing entry.
        5. Addition of new comments
   2. Revisions for (c) and (d) can normally be made without the need for checking.
   3. Revisions for (e) would normally only be made when there is new evidence, new guidance or an important error/omission in the original version. In these cases checking the revised entry would be undertaken.
   4. Any of these changes will require:
      * 1. A change in the section template (with file renaming).
        2. An appropriate entry in the ‘Change’ table,
   5. A new secondary version number (e.g. 2.0 becomes 2.1)
6. **Checking**
   1. Data checking will take place for all new sections, new drugs, and significant ad hoc changes to individual entries where a change in the recommendation or comments is made. Checking will not be required for minor ad hoc changes (e.g. adding an indication or synonym or a consistency change), or for adding a ‘discontinued’ comment (see #5).
   2. The first draft of a new/revised section/entry will be sent to the appropriate clinical checker:
      * 1. PG checked by SF
        2. LK checked by PG
        3. SF currently not writing therefore does not require a checker. *Revisions of SF-written sections will be undertaken by PG.*
   3. After checking the new/revised entries for accuracy and consistency, changes will be added using track changes (for typos etc) or ‘comments’ (for suggested changes to the substance of any entries). The clinical checker’s initials will be added to the file name (see #10).
   4. This process will continue between writer and clinical checker until the final version is agreed. If an agreement cannot be reached, the third person will be consulted.
   5. After agreement of the final version between writer and checker, normally by phone, the writer will produce a final version clean of all track changes and comments (final) and an agreed changes version (TC) for governance purposes, detailing the final changes agreed.
   6. The clinical checking process is detailed fully in [Appendix 4](#App4).
   7. After online data entry/revision by the writer, the online version will be sample checked by the designated checker (DC) – see [Appendix 5](#App5).
7. **Version control**
   1. New sections will start as version 1.0.
   2. Ad hoc revisions (see #7) will have a revised secondary version number (e.g. 1.0 becomes 1.1)
   3. 3-yearly whole section revisions will have a revised primary version number (e.g. 1.0 become 2.0), regardless of whether any changes have been made. The Governance table will be completed with new information.
8. **File naming**
   1. A consistent approach to file naming will be used throughout the whole process to facilitate consistency, version control and governance.
   2. The file name format will follow the convention:
      * BNF *(version 1*) or BM *(version 2)*
      * Chapter and subsection numbers
      * Writer and authors’ initials added sequentially at each stage to identify drafts. This changes to ‘final’ when final version agreed between writer and clinical checker.
   3. Version number (secondary number separated by hyphen  
      For example:  
       BM7-3-2(PG)v2-0  
       BM7-3-2(PG-SF)v2-0  
       BM7-3-2(PG-SF-PG)v2-0  
       BM7-3-2(final)v2-0 *and* BM7-3-2(PG-SF-PG-TC)v2-0  
       BM7-3-2(final-DC)v2-0  
       BM7-3-2(final)v2-0
9. **File storage**
   1. All files, at all stages of checking, will be retained by both writer and checker as a permanent archive.
   2. A separate copy of all final versions or pre-uploaded templates will be stored on the MidMed server and accessible via file hyperlinks embedded in the UKDILAS Database Structure accessible at:  
      [www.midlandsmedicines.nhs.uk/filestore/ukdilas\_files/UKDILAS\_Structure\_Version2\_current.xlsx](http://www.midlandsmedicines.nhs.uk/filestore/ukdilas_files/UKDILAS_Structure_Version2_current.xlsx)
   3. File archives and sharing will be managed by PG.

# PG

# Version 3-0 (draft 2)Appendices

**Appendix 1 Data template (version 7.1)**  

**Appendix 2 Drug name qualifiers** ****

**Appendix 3 Standard phrases** ****

**Appendix 4 Clinical checking procedure** ****

**Appendix 5 Online checking procedure** ****