

## Quality criteria for PILs

### Process indicators

- Evidence of involvement of patients in development
  - o Score 1 for evidence available; 0 for none
- Evidence that needs of special populations have been catered for
  - o Score 1 for discussion of special groups; 0 for none
- User testing carried out/bridged
  - o Score 1 for yes; 0 for no

### Leaflet indicators

#### a. Scores for presentation - text readability and ease of navigation

All scored on a scale of 0 for examples of poor practice, 1 for acceptable, with up to 3 bonus points for examples of best practice on any criteria (max. 1/criterion)

- o font choice, size and style
  - score 0 for difficult to read; 1 for clear and legible
- o use of text in capitals, italics, underlined, in boxes, etc.
  - score 0 for any example of poor use of these; 1 where these are not used
- o contrast between text and background, colour
  - score 0 for poor colour contrast; 1 where good contrast used
- o format and line spacing
  - score 0 for dense text; 1 for good use of white space
- o use of columns, justification and length of lines, sentences and paragraphs
  - score 0 any example of poor use;
- o use of headers
  - score 0 for only the main headings as in the QRD template; bonus for use of clear and sensible headings that aid navigation
- o use of symbols and pictures,
  - score 0 where these are used badly without reference to patients; 1 for good use; bonus when these have good evidence to support their use or clear pictorial instructions for use are included

#### b. Scores for content

All scored on a scale of 0 for poor practice, 1 for acceptable with up to 3 bonus points for examples of best practice on any criteria (max. 1/criterion)

- Pointers to further information sources
  - o Score 0 for no signposting; 1 for signposting
- Pointer to availability in alternative formats
  - o Score 0 for no signposting; 1 for signposting

- Use of lay terms instead of medical jargon
  - o Score 0 where medical jargon persists; 1 for mainly lay terms
- Headline inclusion
  - o Score 0 for no headlines; 1 for headlines
- Inclusion of benefit statement
  - o Score 0 for no benefit information; 1 for appropriate benefit information
- Grouping of side effects:
  - o Score bonus for prominence of key effects with need for action
  - o Score 0 where side effects not broken up at all
  - o Score 0 where system organ class is used
- Inclusion and presentation of side effect frequencies:
  - o Score 0 where no frequencies or word terms not defined

Maximum score for leaflet indicators – 20 (10 for presentation + 10 for content)

### **Outcome indicators**

Aim for concordance - informed actions where any medicine usage is in accordance with dosage instructions and actions required to minimise risk.

Surrogate measures:

- ADR reports relating to incorrect usage
- Information from availability and usage surveys including DH Information Prescription work, published surveys (Raynor, etc.)
- Uptake of DH accreditation (when available)
- Complaints from public and health professionals to MHRA about individual PILs
- Company measures, eg uptake of further information, helpline usage, consumer questions, etc.
- Invited comments from patient organisations, health professionals and public on specific categories as part of planned category reviews