20 September 2017

CMDh/365/2017 Rev.0

QRD form for submission and assessment of user testing bridging proposals

Disclaimer: This form has been developed to provide guidance and facilitate the submission of user testing bridging proposals by applicants as well as to facilitate the assessment by the RMS.

When applying bridging, all sections of this form should be completed by applicants and submitted for assessment.

For assessment purposes, this form should be used in conjunction with the QRD guidance and checklist for the review of user testing results.

PRODUCT INFORMATION

| To be completed by applicant |  |
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| Name of the medicinal product: |  |
| Name and address of the applicant: |  |
| Name of company which has performed the bridging analysis: |  |
| Type of Marketing Authorisation Application: |  |
| Active substance: |  |
| Pharmaco-therapeutic group  (ATC Code): |  |
| Therapeutic indication(s): |  |

1. Grounds for bridging

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| ***To be completed by applicant***  Grounds for bridging based on a sound justification:  extensions for the same route of administration  reference to test with same class of medicinal products  reference to test with same safety issues  reference to test with common design, layout and style of writing  other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Is multiple bridging proposed?  yes  no  Complete the table below for every bridging request:   |  |  |  | | --- | --- | --- | | **Selected ‘parent’ leaflets (Name of the product)** | **Indicate elements used as a basis for bridging, e.g. key safety messages, design/layout, device etc.** | **Route of authorization of parent package leaflet, Procedure number (CAP/NAP) /proof of approval.\*** | | *Example: (Invented) name 1* | *Design/layout* | *EMA/H/…., EPAR* | |  |  |  | |  |  |  | |  |  |  |   \* It has to be stated if, and in which procedure, the user test of the parent leaflet has been assessed and accepted. Procedure number together with evidence (e.g. a copy of the public assessment report for the reference product) should be submitted  Further details: |

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| ***To be completed by assessor***  Are the grounds for using bridging and justification provided by the applicant acceptable?  yes  no  If yes, continue in section 2.  If not, provide further details and recommendation: |

### Guidance regarding grounds for bridging

The term ‘bridging’ is used to describe the situation where, because the leaflets are sufficiently similar in both content and layout, a successful user consultation on one leaflet can be used to demonstrate that another leaflet meets the requirements of article 59(3) of Council Directive 2001/83/EC.

In bridging, a successful user test on one PL (the ‘parent’ PL) can be used to support a justification for not testing other similar leaflets (‘daughter’ PLs). In some circumstances it may be appropriate for some ‘daughter’ PLs to rely on the results of testing for more than one ‘parent’ PL (multiple bridging). For example, it would be possible to refer to the design and layout of one leaflet and to the content of the leaflet for another product. However, a maximum of 3 bridging procedures could be accepted for one product: e.g. first bridging to address the scientific content, a second one to address the device and a last one to address the design/layout of the PL.

Bridging proposals should always be accompanied by a sound justification and the grounds for bridging assessed on a case by case basis.

1. Comparison of ‘parent’ and ‘daughter’ package leaflet(s)

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| ***To be completed by applicant***   * 1. **Is bridging proposed for design/layout/format?**  **yes**  **no**   - Real size mock-up(s) of ‘parent’ leaflet(s) provided?  yes  no  - Real size mock-up of ‘daughter’ leaflet provided?  yes  no   |  |  |  | | --- | --- | --- | | **Key elements** | **Critical comparison\*** | **Assessment (to be completed by assessor)**  *(acceptable/not acceptable)* | | **Font and text size** |  |  | | **Headings and sub-headings including formatting consistency.** |  |  | | **Leaflet dimensions including whether the document is laid out in portrait or landscape format.** |  |  | | **Use of colour and choice of colour.** |  |  | | **Style of writing and language used.** |  |  | | **Layout of critical safety sections of the leaflet** |  |  | | **Use of pictograms** |  |  | | \* The critical appraisal should include a detailed comparison of all key readability elements between parent and daughter leaflets and consider how they are supported by the parent user test. Any differences on key readability elements between parent and daughter leaflets and any measures taken to address them (e.g. focus test) should also be indicated. | | |   Further details/applicant’s conclusion: |

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| ***To be completed by assessor***  Have all differences on key elements between parent and daughter package leaflets been identified?  yes  no  n/a  If so, have they been correctly addressed (e.g. with a focus test)?  yes  no  Further details:  Is bridging acceptable for the design/layout/format of ‘daughter’ package leaflet?  yes  no  Conclusion/recommendation: |

**Guidance regarding comparison of design/layout/format**

Real size mock-ups should be provided in order to allow for accurate comparison between ‘parent’ and ‘daughter’ leaflets, in particular when bridging is applied for design/layout/format.

Since the design and layout of the information is crucial to how the information is used and understood, ‘daughter’ leaflets should be of the same design, layout and writing style as the ‘parent’ leaflet in order for bridging to be successful.

Paper weight may not be possible to assess at the time of review of bridging proposals. However, this is an aspect that should be addressed by the applicant within the bridging justification (e.g. ensuring that same paper is used in final specimens or providing an acceptable justification for the use of different paper).

The date of original user consultation and any revisions of the package leaflet that may have resulted in modification of key elements of the parent package leaflet (i.e. design/layout/format/wording) should be taken into consideration during the evaluation of the suitability of bridging proposals.

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| **To be completed by applicant**  **2.2. Is bridging proposed for content?**  **yes**  **no**  Please identify key safety messages of both ‘parent’ and ‘daughter’ leaflets and state actual wording in the table below. A critical appraisal of any differences identified as well as of synergies and similarities in the key messages should be provided. The relevance of the user testing questionnaire to the “daughter” leaflet should also be addressed.   |  |  |  |  | | --- | --- | --- | --- | | **Section in PL** | **‘Parent’ leaflet** | **‘Daughter’ leaflet** | **Critical appraisal** | |  |  |  |  | |  |  |  |  | |  |  |  |  |   *(Add additional rows as necessary)*  Further details/applicant’s conclusion: |

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| ***To be completed by assessor***  Have **all** key safety messages been correctly identified?  yes no  Provide further details:  Have any differences in key safety messages been identified by the applicant?  yes no  If so, have differences been correctly addressed (i.e. with a focus test)?  yes no  Provide further details:  Have any relevant differences in wording been adequately justified by the applicant? yes no  Provide further details:  Is bridging acceptable for the content of ‘daughter’ package leaflet?  yes  no  Conclusion/recommendation: |

**Guidance regarding comparison of content**

When bridging is applied to content, key safety messages should have been correctly identified during user consultation of ‘parent’ package leaflet(s) in order to ensure that ‘daughter’ package leaflet(s) have similar (not necessarily identical) key safety messages in patient friendly language. Such user consultation could then be relied upon to support a package leaflet drawn up in the same manner for a closely related medicine.

The date of original user consultation and any revisions of the package leaflet that may have resulted in modification of key elements (i.e key safety messages) of the parent package leaflet should be taken into consideration during the evaluation of the suitability of bridging proposals.

1. Conclusion of assessment and recommendations

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| ***To be completed by assessor and reflected in Assessment Report***  Has the applicant demonstrated that the ‘parent’ and ‘daughter’ leaflet(s) are sufficiently similar for bridging?  yes  no  Does the package leaflet meet the criteria set out in Art 59(3) of Directive 2001/83/EC?  yes  no  OVERALL CONCLUSION/RECOMMENDATIONS: |

1. Attachments

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| ***To be completed by applicant***  Please tick the appropriate where applicable:  Real size mock-up of ‘daughter’ package leaflet(s)  Real size mock-up of ‘parent’ package leaflet(s)  EPAR of ‘parent’ package leaflet(s) |