

Active Substance:

Applicant:

Date:

APPENDIX 11
FORMS FOR USE IN CHECKING DOSSIERS FOR COMPLETENESS

Part 2 Evaluation Form 2 -
for use in checking that the required Annex II and Annex III dossier summaries and an overall assessment,
have been provided

Active Substance:

Applicant:

Date:

Document	Description of the document	Document provided	Data gap
L-II	Annex II, <i>Tier I</i> reports as to the quality of individual test and study reports		<input type="checkbox"/>
L	Reference List: Listing of test and study reports, test guidelines and published papers relevant to the Annex II dossier:		
L IIa	- papers and reports submitted listed by Annex point		<input type="checkbox"/>
L IIb	- papers and reports submitted listed by alphabetically by author		<input type="checkbox"/>
L IIc	- list of papers and reports not submitted, arranged alphabetically by author		<input type="checkbox"/>
M-II	Annex II, <i>Tier II</i> dossier summary and overall assessment		<input type="checkbox"/>
L-III	Annex III, <i>Tier I</i> reports as to the quality of individual test and study reports for each Annex III dossier submitted		
L-III a	* First preparation		<input type="checkbox"/>
L-III b	* Second preparation		<input type="checkbox"/>
L-III c	* Third preparation		<input type="checkbox"/>
L-III d	* Fourth preparation		<input type="checkbox"/>
L	Reference List: Listing of test and study reports, test guidelines and published papers relevant to each Annex III dossier:		
	* First preparation		
L III e	- papers and reports submitted listed by Annex point		<input type="checkbox"/>
L III f	- papers and reports submitted listed by alphabetically by author		<input type="checkbox"/>
L III g	- list of papers and reports not submitted, arranged alphabetically by author		<input type="checkbox"/>
	* Second preparation		
L III h	- papers and reports submitted listed by Annex point		<input type="checkbox"/>
L III i	- papers and reports submitted listed by alphabetically by author		<input type="checkbox"/>
L III j	- list of papers and reports not submitted, arranged alphabetically by author		<input type="checkbox"/>
	* Third preparation		
L III k	- papers and reports submitted listed by Annex point		<input type="checkbox"/>
L III l	- papers and reports submitted listed by alphabetically by author		<input type="checkbox"/>
L III m	- list of papers and reports not submitted, arranged alphabetically by author		<input type="checkbox"/>
	* Fourth preparation		
L III n	- papers and reports submitted listed by Annex point		<input type="checkbox"/>
L III o	- papers and reports submitted listed by alphabetically by author		<input type="checkbox"/>
L III p	- list of papers and reports not submitted, arranged alphabetically by author		<input type="checkbox"/>
M-III	Annex III, <i>Tier II</i> dossier summary and overall assessment		
M-III a	* First preparation		<input type="checkbox"/>
M-III b	* Second preparation		<input type="checkbox"/>
M-III c	* Third preparation		<input type="checkbox"/>
M-III d	* Fourth preparation		<input type="checkbox"/>
N	An overall summary and assessment of the application		<input type="checkbox"/>