JOINT EMEA/EFPIA QUESTIONNAIRE ON THE NEW EUROPEAN REGISTRATION SYSTEM
- CENTRALISED PROCEDURE -

- **GENERAL INFORMATION (Questions 1 – 15 to be answered by: EMEA, Applicant)**

1. Name of the Applicant: _____
2. Country of the Applicant: _____
3. Person to be contacted for further information (optional):_____
4. Phone number: _____ Fax number: _____
5. Name of the Rapporteur: _____
6. Name of the Co-Rapporteur: _____
7. Name of the EMEA Project Manager: _____

- **PRODUCT INFORMATION**

8. Name of the medicinal product: _____
9. Name of the active substance(s): _____
10. EMEA procedure no.: _____
11. Pharmacotherapeutic classification (ATC system): _____
12. Pharmaceutical form: _____ Strength: _____
13. Status of the product: ❑ Part A ❑ Part B

14. Basis for Part A status**:**

    ❑ recombinant DNA technology
    ❑ controlled expression of genes coding for biologically active proteins
    ❑ hybridoma and monoclonal antibody methods

15. Basis of Part B status:

    ❑ other innovative biotechnical processes
    ❑ innovative new delivery system
    ❑ novel indication
    ❑ based on radio-isotope which is of significant therapeutic interest
    ❑ derived from human blood/plasma
    ❑ manufacturing process which demonstrates a significant technical advance
    ❑ new active substance
    ❑ others

** Please indicate level of satisfaction by scoring between 1 and 4. 1 : very dissatisfied, 2 : dissatisfied, 3 : satisfied, 4 : very satisfied*
*****Answer by : A = Applicant, B = EMEA, C = Rapporteur***
Please add supplementary sheets as necessary

- **SCIENTIFIC ADVICE (Questions 16 – 18.2 to be answered by the Applicant only)**

16. During the development process before submission to the EMEA, was Scientific Advice sought from the CPMP?

❑ yes ❑ no

16.1 If yes, in which area was Scientific Advice sought?

Quality	❑
Biotechnology	❑
Safety	❑
Efficacy	❑

16.2. If yes, how useful was this Scientific Advice?*

❑ 1 ❑ 2 ❑ 3 ❑ 4

Comments: _____
_____

17. Did this advice influence the following steps?

1) Development of the product ❑ yes ❑ no

Comments: _____
_____

2) Subsequent assessment of the dossier ❑ yes ❑ no

Comments: _____
_____

18. Did you seek Scientific Advice from national authorities prior to this request?

❑ yes ❑ no

18.1 If yes, in which country(ies)? _____

18.2 If yes, was this advice of additional help?

❑ yes ❑ no

Comments: _____
_____
_____
_____

** Please indicate level of satisfaction by scoring between 1 and 4. 1 : very dissatisfied, 2 : dissatisfied, 3 : satisfied, 4 : very satisfied*

*****Answer by : A = Applicant, B = EMEA, C = Rapporteur***

Please add supplementary sheets as necessary

DAY	STAGE OF PROCEDURE	See **	QUESTION	ANSWER
Not later than -120	EMEA/CPMP notified by letter of intended submission - foreseen date for submission - justification of part A or B status - proposals for 3-4 Rapporteurs	A	19. Proposed Rapporteurs (nationally)	19. _____ _____
	- Identification of possible problems (Trade Mark, User Patient Leaflet, Legal Status, Inspection, Drug Master File, ...)	A	20. Identification of "possible problems" by the EMEA	20._____ _____ _____
		A	20.1 If yes, date of notification to the company	20.1 ☐☐ ☐☐ ☐☐ Day Month Year
-90 appr.	After CPMP review, the EMEA notifies the Applicant of - confirmation of Part A or B status - choice of Rapporteur and Co-Rapporteur - name of Project Manager	A	21. Date of receipt of notification of the names of Rapporteur, Co-Rapporteur and Project Manager and identification of fee to be paid	21. ☐☐ ☐☐ ☐☐ Day Month Year
		A	22. Are you satisfied with the choice of the Rapporteur/Co-Rapporteur?	22. ❑ Yes ❑ No
		A	22.1 If no, please give comments	22.1 _____ _____ _____

** Please indicate level of satisfaction by scoring between 1 and 4. 1 : very dissatisfied, 2 : dissatisfied, 3 : satisfied, 4 : very satisfied*

****Answer by : A = Applicant, B = EMEA, C = Rapporteur***

Please add supplementary sheets as necessary

Not later than -15	- Possible pre-submission meeting with the EMEA	A + B + C	23. Did a pre-submission meeting take place 1) with the EMEA only (administrative/ regulatory issues)? If yes, when? 2) with Rapporteur and Co-Rapporteur and the EMEA (scientific issues)? If yes, when? 3) with Rapporteur only at national level? If yes, when? 4) with Co-Rapporteur only at national level? If yes, when? 5) with Rapporteur and Co-Rapporteur jointly at national level? If yes, when?	23. 1) ❑ Yes ❑ No ☐☐ ☐☐ ☐☐ Day Month Year 2) ❑ Yes ❑ No ☐☐ ☐☐ ☐☐ Day Month Year 3) ❑ Yes ❑ No ☐☐ ☐☐ ☐☐ Day Month Year 4) ❑ Yes ❑ No ☐☐ ☐☐ ☐☐ Day Month Year 5) ❑ Yes ❑ No ☐☐ ☐☐ ☐☐ Day Month Year

** Please indicate level of satisfaction by scoring between 1 and 4. 1 : very dissatisfied, 2 : dissatisfied, 3 : satisfied, 4 : very satisfied*

*****Answer by : A = Applicant, B = EMEA, C = Rapporteur***

Please add supplementary sheets as necessary

		A + C	24. Quality of the meeting with regard to organisation, facilities and timing* 1) with the EMEA 2) with Rapporteur and Co-Rapporteur and the EMEA 3) with Rapporteur only at national level 4) with Co-Rapporteur only at national level 5) with Rapporteur and Co-Rapporteur jointly at national level	24. 1) ❑ 1 ❑ 2 ❑ 3 ❑ 4 2) ❑ 1 ❑ 2 ❑ 3 ❑ 4 3) ❑ 1 ❑ 2 ❑ 3 ❑ 4 4) ❑ 1 ❑ 2 ❑ 3 ❑ 4 5) ❑ 1 ❑ 2 ❑ 3 ❑ 4 Comments: _____
		A + B + C	25. Please qualify the usefulness of the meeting(s)* 1) with the EMEA only 2) with Rapporteur and Co-Rapporteur and the EMEA 3) with Rapporteur only at national level 4) with Co-Rapporteur only at national level 5) with Rapporteur and Co-Rapporteur jointly at national level	25. 1) ❑ 1 ❑ 2 ❑ 3 ❑ 4 2) ❑ 1 ❑ 2 ❑ 3 ❑ 4 3) ❑ 1 ❑ 2 ❑ 3 ❑ 4 4) ❑ 1 ❑ 2 ❑ 3 ❑ 4 5) ❑ 1 ❑ 2 ❑ 3 ❑ 4 Comments: _____
		A + C	26. Were any problems identified during the meeting which could have led to major objections during the assessment of the file?	26. ❑ Yes ❑ No

** Please indicate level of satisfaction by scoring between 1 and 4. 1 : very dissatisfied, 2 : dissatisfied, 3 : satisfied, 4 : very satisfied*

*****Answer by : A = Applicant, B = EMEA, C = Rapporteur***

Please add supplementary sheets as necessary

		A + C	26.1 If yes, please give comments	26.1 _____ _____ _____
		A + B	27. Have you been requested by the EMEA to provide further information?	27. ❑ Yes ❑ No
		A + B	28. If yes, in what category and give brief details	28. ❑ Administrative data: _____ _____ _____ ❑ Quality: _____ _____ _____ ❑ Non clinical Safety: _____ _____ _____ ❑ Clinical Safety: _____ _____ _____ ❑ Efficacy: _____ _____ _____

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*****Answer by : A = Applicant, B = EMEA, C = Rapporteur***

Please add supplementary sheets as necessary

Not later than -15	- Submission of the application to the EMEA	A	29. Date of submission of the application	29. ☐☐ Day ☐☐ Month ☐☐ Year
		B	30. Date of receipt of the dossier	30. ☐☐ Day ☐☐ Month ☐☐ Year
	- Validation of the application	A + B	31. Were any problems identified during the validation phase?	31. ❑ Yes ❑ No
		A + B	31.1 If yes, please give comments	31.1 _____ _____ _____

1	Start of procedure	A + B	32. Date of start of the procedure	32. ☐☐ Day ☐☐ Month ☐☐ Year
70	Date of receipt of the Assessment Reports (AR) from Rapporteur/Co-Rapporteur by CPMP/EMEA and Applicant	A + B	33. Date of receipt of the AR 1) from Rapporteur	33. 1) ☐☐ Day ☐☐ Month ☐☐ Year
			2) from Co-Rapporteur	2) ☐☐ Day ☐☐ Month ☐☐ Year
		A + B	34. Quality of the Rapporteur's AR* 1) Quality part 2) Safety part 3) Efficacy part	34. 1) ❑ 1 ❑ 2 ❑ 3 ❑ 4 2) ❑ 1 ❑ 2 ❑ 3 ❑ 4 3) ❑ 1 ❑ 2 ❑ 3 ❑ 4

** Please indicate level of satisfaction by scoring between 1 and 4. 1 : very dissatisfied, 2 : dissatisfied, 3 : satisfied, 4 : very satisfied*

****Answer by : A = Applicant, B = EMEA, C = Rapporteur***

Please add supplementary sheets as necessary

		A + B	35. Quality of the Co-Rapporteur's AR* 1) Quality part 2) Safety part 3) Efficacy part	35. 1) ❑ 1 ❑ 2 ❑ 3 ❑ 4 2) ❑ 1 ❑ 2 ❑ 3 ❑ 4 3) ❑ 1 ❑ 2 ❑ 3 ❑ 4
		A + B	36. Clarity of the issues raised in the AR*	36. ❑ 1 ❑ 2 ❑ 3 ❑ 4 Comments: _____ _____ _____
		C	37. Quality of the dossier* 1) Quality 2) Safety 3) Efficacy	37. 1) ❑ 1 ❑ 2 ❑ 3 ❑ 4 2) ❑ 1 ❑ 2 ❑ 3 ❑ 4 3) ❑ 1 ❑ 2 ❑ 3 ❑ 4 Comments: _____ _____ _____
		C	38. Quality of the expert reports provided by the Applicant* 1) Quality 2) Safety 3) Efficacy	38. 1) ❑ 1 ❑ 2 ❑ 3 ❑ 4 2) ❑ 1 ❑ 2 ❑ 3 ❑ 4 3) ❑ 1 ❑ 2 ❑ 3 ❑ 4 Comments: _____ _____ _____

** Please indicate level of satisfaction by scoring between 1 and 4. 1 : very dissatisfied, 2 : dissatisfied, 3 : satisfied, 4 : very satisfied*

*****Answer by : A = Applicant, B = EMEA, C = Rapporteur***

Please add supplementary sheets as necessary

		A + C	39. In the case of Scientific Advice being given by the CPMP, to what extent was it followed in the development of the product and preparation of the file?*	39. ❑ 1 ❑ 2 ❑ 3 ❑ 4
		A + C	39.1 Please give comments	39.1 _____
		C	39.2 To what extent did the Scientific Advice facilitate the assessment of the dossier?*	39.2 ❑ 1 ❑ 2 ❑ 3 ❑ 4
		B + C	40. Quality of the SPC*	40.
			1) Quality of English version	1) ❑ 1 ❑ 2 ❑ 3 ❑ 4
			2) Consistency with expert reports	2) ❑ 1 ❑ 2 ❑ 3 ❑ 4
		B + C	41. Quality of the Package Leaflet*	41.
			1) Consistency with SPC	1) ❑ 1 ❑ 2 ❑ 3 ❑ 4
			2) Quality of English version	2) ❑ 1 ❑ 2 ❑ 3 ❑ 4
			3) Understandable wording for patients	3) ❑ 1 ❑ 2 ❑ 3 ❑ 4
		B + C	42. Quality of the Labelling*	42.
			1) Wording	1) ❑ 1 ❑ 2 ❑ 3 ❑ 4
			2) Consistency with legislation	2) ❑ 1 ❑ 2 ❑ 3 ❑ 4
		B	43. Quality of the translations of SPC, Package Leaflet and Labelling*	43. ❑ 1 ❑ 2 ❑ 3 ❑ 4
		B	44. In the case of major difficulties, please identify the issues and the language(s)	44. _____

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*****Answer by : A = Applicant, B = EMEA, C = Rapporteur***

Please add supplementary sheets as necessary

100	Receipt of comments from CPMP Members	B	45. Comments by CPMP Members on AR due on	45. ☐☐ ☐☐ ☐☐ Day Month Year
		B	46. Number of CPMP Members who provided comments to Rapporteur and Co-Rapporteur	46. ☐☐
		C	47. Were any additional major objections identified?	47. ❑ Yes ❑ No

120	- CPMP validates and EMEA provides list of questions, overall conclusions and executive summary to Applicant - If needed, clock stop	B	48. Date of CPMP adoption of list of questions	48. ☐☐ ☐☐ ☐☐ Day Month Year
		A	49. Date of receipt of list of questions	49. ☐☐ ☐☐ ☐☐ Day Month Year
		A	50. Clarity of list of questions, overall conclusions and executive summary*	50. ❑ 1 ❑ 2 ❑ 3 ❑ 4 Comments: _____ _____ _____
		A + B + C	51. Please specify if overall conclusions indicated whether the product was approvable or non approvable	51. ❑ No indication ❑ Approvable ❑ Non Approvable

** Please indicate level of satisfaction by scoring between 1 and 4. 1 : very dissatisfied, 2 : dissatisfied, 3 : satisfied, 4 : very satisfied*

*****Answer by : A = Applicant, B = EMEA, C = Rapporteur***

Please add supplementary sheets as necessary

		A + C	52. If the product was approvable, in which areas were there questions to be answered?	52. ❑ Quality ❑ Pre-clinical Safety ❑ Clinical Safety ❑ Efficacy
		A + C	53. If the product was not approvable, in which areas were there major objections to be addressed?	53. ❑ Quality ❑ Pre-clinical Safety ❑ Clinical Safety ❑ Efficacy
		A + C	53.1 Were any of these questions related to an issue for which Scientific Advice had been requested?	53.1 ❑ Yes ❑ No Comments:_____
		A + C	54. Did the CPMP reconsider their initial Scientific Advice?	54. ❑ Yes ❑ No
		C	54.1 If yes, please give details	54.1 _____
		A	55. If the CPMP reconsidered their Scientific Advice, do you think it was justified?	55. ❑ Yes ❑ No
		A	55.1 If no, please give comments	55.1 _____
		A + B	56. Date of the clock stop (if applicable)	56. ☐☐ ☐☐ ☐☐ Day Month Year

** Please indicate level of satisfaction by scoring between 1 and 4. 1 : very dissatisfied, 2 : dissatisfied, 3 : satisfied, 4 : very satisfied*

*****Answer by : A = Applicant, B = EMEA, C = Rapporteur***

Please add supplementary sheets as necessary

		A + B + C	57. Was a meeting needed for preparing answers 1) with the EMEA only? If yes, when did it take place?	57. 1) ❑ Yes ❑ No ☐☐ ☐☐ ☐☐ Day Month Year
			2) with Rapporteur and Co-Rapporteur and the EMEA? If yes, when did it take place?	2) ❑ Yes ❑ No ☐☐ ☐☐ ☐☐ Day Month Year
			3) with Rapporteur only at national level? If yes, when did it take place?	3) ❑ Yes ❑ No ☐☐ ☐☐ ☐☐ Day Month Year
			4) with Co-Rapporteur only at national level? If yes, when did it take place?	4) ❑ Yes ❑ No ☐☐ ☐☐ ☐☐ Day Month Year
			5) with Rapporteur and Co-Rapporteur jointly at national level If yes, when did it take place?	5) ❑ Yes ❑ No ☐☐ ☐☐ ☐☐ Day Month Year

** Please indicate level of satisfaction by scoring between 1 and 4. 1 : very dissatisfied, 2 : dissatisfied, 3 : satisfied, 4 : very satisfied*

*****Answer by : A = Applicant, B = EMEA, C = Rapporteur***

Please add supplementary sheets as necessary

		A	58. Quality of the meeting with regard to organisation, facilities and timing* 1) with the EMEA only 2) with the EMEA, Rapporteur and Co-Rapporteur 3) with Rapporteur only at national level 4) with Co-Rapporteur only at national level 5) with Rapporteur and Co-Rapporteur jointly at national level	58. 1) ❑ 1 ❑ 2 ❑ 3 ❑ 4 2) ❑ 1 ❑ 2 ❑ 3 ❑ 4 3) ❑ 1 ❑ 2 ❑ 3 ❑ 4 4) ❑ 1 ❑ 2 ❑ 3 ❑ 4 5) ❑ 1 ❑ 2 ❑ 3 ❑ 4 Comments: _____ _____ _____
		A + C A A + C A + C A + C A + C	59. Please qualify the usefulness of the meeting(s) with respect to scientific discussion and added value* 1) with the EMEA only 2) with Rapporteur and Co-Rapporteur and the EMEA 3) with Rapporteur only at national level 4) with Co-Rapporteur only at national level 5) with Rapporteur and Co-Rapporteur jointly at national level	59. 1) ❑ 1 ❑ 2 ❑ 3 ❑ 4 2) ❑ 1 ❑ 2 ❑ 3 ❑ 4 3) ❑ 1 ❑ 2 ❑ 3 ❑ 4 4) ❑ 1 ❑ 2 ❑ 3 ❑ 4 5) ❑ 1 ❑ 2 ❑ 3 ❑ 4 Comments: _____ _____ _____

** Please indicate level of satisfaction by scoring between 1 and 4. 1 : very dissatisfied, 2 : dissatisfied, 3 : satisfied, 4 : very satisfied*

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Please add supplementary sheets as necessary

121	- Submission of written responses and new draft of English SPC, Package Leaflet and Labelling by the Applicant to Rapporteur, Co-Rapporteur, CPMP Members and the EMEA - Restart of the clock	A	60. Date of submission of the responses	60. ☐☐ ☐☐ ☐☐ Day Month Year
		A + C	61. Did the Applicant have any difficulties in providing responses within the time frame proposed by the CPMP?	61. ❑ Yes ❑ No
		A + C	61.1 If yes, please give comments	61.1 _____ _____ _____
		A + B	62. Date of restart of the clock	62. ☐☐ ☐☐ ☐☐ Day Month Year
		C	63. Quality of the responses* 1) Quality 2) Pre-clinical Safety 3) Clinical Safety 4) Efficacy	63. 1) ❑ 1 ❑ 2 ❑ 3 ❑ 4 2) ❑ 1 ❑ 2 ❑ 3 ❑ 4 3) ❑ 1 ❑ 2 ❑ 3 ❑ 4 4) ❑ 1 ❑ 2 ❑ 3 ❑ 4 Comments: _____ _____ _____

** Please indicate level of satisfaction by scoring between 1 and 4. 1 : very dissatisfied, 2 : dissatisfied, 3 : satisfied, 4 : very satisfied*

****Answer by : A = Applicant, B = EMEA, C = Rapporteur***

Please add supplementary sheets as necessary

150	Assessment Report on the responses to the list of questions	A + B	64. Date of receipt of the AR	64. ☐☐ Day ☐☐ Month ☐☐ Year
		A + B	65. Clarity of the AR on the responses*	65. ❑ 1 ❑ 2 ❑ 3 ❑ 4 Comments: _____
	Checking of new draft of English SPC, Package Leaflet and Labelling	B + C	66. Quality* (according to format, allowed terms, consistency within documents...) of the 1) SPC 2) Package Leaflet 3) Labelling	66. 1) ❑ 1 ❑ 2 ❑ 3 ❑ 4 2) ❑ 1 ❑ 2 ❑ 3 ❑ 4 3) ❑ 1 ❑ 2 ❑ 3 ❑ 4
		B	67. Quality of the translations 1) SPC 2) Package Leaflet 3) Labelling	67. 1) ❑ 1 ❑ 2 ❑ 3 ❑ 4 2) ❑ 1 ❑ 2 ❑ 3 ❑ 4 3) ❑ 1 ❑ 2 ❑ 3 ❑ 4
		B	68. If difficulties were encountered, in which language? Please comment.	68._____

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****Answer by : A = Applicant, B = EMEA, C = Rapporteur***

Please add supplementary sheets as necessary

170	Deadline for comments from CPMP Members back to Rapporteur and Co-Rapporteur	B	69. Please specify the date	69. ☐☐ ☐☐ ☐☐ Day Month Year
		B	70. Was the deadline respected?	70. ❑ Yes ❑ No
		B	70.1 If no, please specify	70.1 _____ _____ _____ _____
		B	71. Number of CPMP Members who provided comments to Rapporteur and Co-Rapporteur	71. ☐☐
		B+ C	72. Number of CPMP Members with new out-standing major objections	72. ☐☐

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****Answer by : A = Applicant, B = EMEA, C = Rapporteur***

Please add supplementary sheets as necessary

170 - 180	CPMP discussion and decision on the need for an oral explanation by the Applicant	A + B	73. Was an oral explanation requested? If yes, when?	73. ❑ Yes ❑ No ☐☐ ☐☐ ☐☐ Day Month Year
		A + B + C	73.1 If yes, 1) on request of the Applicant? 2) on request of the CPMP? 3) upon advice of the Rapporteur?	73.1 1) ❑ 2) ❑ 3) ❑
		A + B + C	73.2 If yes, please specify the reasons	73.2 _____ _____ _____
		A	73.3 On which part of the dossier? 1) Quality 2) Preclinical Safety 3) Efficacy 4) Clinical Safety	73.3 1) ❑ 2) ❑ 3) ❑ 4) ❑
		A + B	74. Date of the clock stop, if requested	74. ☐☐ ☐☐ ☐☐ Day Month Year ☐☐ ☐☐ ☐☐
		A + C	75. Was a preparatory meeting with Rapporteur, Co-Rapporteur and Project Manager organised?	75. ❑ Yes ❑ No
		A + C	75.1 If yes, how useful was the meeting?*	75.1 ❑ 1 ❑ 2 ❑ 3 ❑ 4 Comments: _____ _____ _____

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*****Answer by : A = Applicant, B = EMEA, C = Rapporteur***

Please add supplementary sheets as necessary

181	Restart of the clock and oral explanation	A + B	76. Date of restart of the clock/oral explanation	76. ☐☐ Day ☐☐ Month ☐☐ Year
		A + C	77. Quality of the oral explanation* 1) with regard to the scientific discussion of outstanding major objections 2) with regard to organisation, facilities, timing	77. 1) ❑ 1 ❑ 2 ❑ 3 ❑ 4 2) ❑ 1 ❑ 2 ❑ 3 ❑ 4 Comments: _____
		A	78. Were the issues resolved during the oral explanation?	78. ❑ Yes ❑ No
		A	78.1 If no, please give further comments	78.1 _____
		C	79. Quality of the presentation given by the Applicant during the oral explanation*	79. ❑ 1 ❑ 2 ❑ 3 ❑ 4 Comments: _____
		A + C	80. Do you think the oral explanation was useful?	80. ❑ Yes ❑ No

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*****Answer by : A = Applicant, B = EMEA, C = Rapporteur***

Please add supplementary sheets as necessary

BEF 210	CPMP Opinion + CPMP draft AR	A + B	81. Date of CPMP Opinion	81. ☐☐ ☐☐ ☐☐ Day Month Year
		A	82. Please indicate any changes (and section concerned) between SPC, Package Leaflet and Labelling applied for and approved	82. _____ _____ _____ _____
BEF 240	Translations sent by the Applicant to CPMP Members and the EMEA. Finalisation of CPMP AR to be transmitted to the Applicant	A	83. Date of receipt of final AR	83. ☐☐ ☐☐ ☐☐ Day Month Year
		B	84. Date of receipt of final SPC, Package Leaflet and Labelling in all eleven languages	84. ☐☐ ☐☐ ☐☐ Day Month Year
		A+B	85. Receipt of last comments on translations from CPMP Members	85. ☐☐ ☐☐ ☐☐ Day Month Year
			1) In time	1). ❑ Yes ❑ No
			2) If a delay, how many maximum number of days?	2) ☐☐
			3) Number of delegations having sent comments on translations to the applicant and the EMEA.	3) ☐☐
			4) Comments	4)_____ _____ _____ —
		A	86. Relevance of their comments*	86. ❑ 1 ❑ 2 ❑ 3 ❑ 4
		B	87. Deadline for the Applicant to provide final SPC, Package Leaflet and Labelling in all eleven languages	87. ☐☐ ☐☐ ☐☐ Day Month Year

** Please indicate level of satisfaction by scoring between 1 and 4. 1 : very dissatisfied, 2 : dissatisfied, 3 : satisfied, 4 : very satisfied*

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Please add supplementary sheets as necessary

		B	88. Date of receipt of finalised SPC, Package Leaflet and Labelling from the Applicant (receipt of <u>all</u> translations in <u>all</u> languages)	88. ☐☐ ☐☐ ☐☐ Day Month Year
BEF 240	Transmission of Opinion to Applicant, Commission and Member States in all languages	B	89. Date of transmission of Opinion in all languages to the 1) Applicant 2) Commission 3) Member States	89. 1) ☐☐ ☐☐ ☐☐ Day Month Year 2) ☐☐ ☐☐ ☐☐ Day Month Year 3) ☐☐ ☐☐ ☐☐ Day Month Year
		B	90. Reason for delay, if applicable	90. _____ _____ _____
		B	91. Date of receipt of Commission's acknowledgement at the EMEA	91. ☐☐ ☐☐ ☐☐ Day Month Year

** Please indicate level of satisfaction by scoring between 1 and 4. 1 : very dissatisfied, 2 : dissatisfied, 3 : satisfied, 4 : very satisfied*

****Answer by : A = Applicant, B = EMEA, C = Rapporteur***

Please add supplementary sheets as necessary

BEF 300	Finalisation of EPAR in consultation with CPMP, Rapporteur, Co-Rapporteur and Applicant	B	92. Date of receipt of proposal from the Applicant concerning the deletion of confidential data	92. ☐☐ ☐☐ ☐☐ Day Month Year
		B	93. Date of circulation of draft 1 of EPAR to the CPMP and the Applicant	93. ☐☐ ☐☐ ☐☐ Day Month Year
		B	94. Was the deadline for comments on draft 1 of the EPAR respected?	94. ❑ Yes ❑ No
		B	94.1 If no, who did not respect it?	94.1 ❑ Applicant ❑ CPMP
		A + B	94.2 In the event of difficulties, comment	94.2_____
		B	95. Date of CPMP adoption of draft 2 of EPAR	95. ☐☐ ☐☐ ☐☐ Day Month Year

** Please indicate level of satisfaction by scoring between 1 and 4. 1 : very dissatisfied, 2 : dissatisfied, 3 : satisfied, 4 : very satisfied*

****Answer by : A = Applicant, B = EMEA, C = Rapporteur***

Please add supplementary sheets as necessary

		A + C	96. Final EPAR. Are you satisfied with* 1) Objectiveness	96. 1) ❑ 1 ❑ 2 ❑ 3 ❑ 4 Comments: _____ _____ _____
		A + C	2) Clarity and legibility	2) ❑ 1 ❑ 2 ❑ 3 ❑ 4 Comments: _____ _____ _____
		A	3) Level of data protection	3) ❑ 1 ❑ 2 ❑ 3 ❑ 4 Comments: _____ _____ _____
		A + B	97. Date of Commission Decision	97. ☐☐ ☐☐ ☐☐ Day Month Year
		B	98. Date of notification of the Commission Decision to the Applicant	98. ☐☐ ☐☐ ☐☐ Day Month Year
		B	99. Date of transmission of the EPAR to the Applicant	99. ☐☐ ☐☐ ☐☐ Day Month Year
		B	100. Date of availability of the EPAR to the public	100. ☐☐ ☐☐ ☐☐ Day Month Year

** Please indicate level of satisfaction by scoring between 1 and 4. 1 : very dissatisfied, 2 : dissatisfied, 3 : satisfied, 4 : very satisfied*

****Answer by : A = Applicant, B = EMEA, C = Rapporteur***

Please add supplementary sheets as necessary

OVERALL OVERVIEW:

101. Are you satisfied with the procedure as such?*

❑ 1 ❑ 2 ❑ 3 ❑ 4 (to be answered by the Applicant)

❑ 1 ❑ 2 ❑ 3 ❑ 4 (to be answered by the Rapporteur)

102. Are you satisfied with transparency, dialogue and advice* from

1) the EMEA

❑ 1 ❑ 2 ❑ 3 ❑ 4 (to be answered by the Applicant)

2) the Rapporteur/Co-Rapporteur

❑ 1 ❑ 2 ❑ 3 ❑ 4 (to be answered by the Applicant)

103. Are you satisfied with transparency, dialogue and assistance from the EMEA?*

❑ 1 ❑ 2 ❑ 3 ❑ 4 (to be answered by the Rapporteur)

104. Other Comments: _____
_____
_____
_____
_____
_____

Filled in by..... Date.....

** Please indicate level of satisfaction by scoring between 1 and 4. 1 : very dissatisfied, 2 : dissatisfied, 3 : satisfied, 4 : very satisfied*

****Answer by : A = Applicant, B = EMEA, C = Rapporteur***

Please add supplementary sheets as necessary