



1 December 2016
EMA/726171/2016
Veterinary Medicines Division

Recommended submission dates

Centralised (initial and extension applications) and MRL procedures – 1st phase (120-day assessment)

Submission date	Validation of dossier completed	Start (day 1)	Rapporteur's AR	Co-rapporteur's comments	Comments from CVMP members including peer review	Draft list of questions	Rapporteur's meeting (teleconference)	Adoption of list of questions (day 120)
2016								
22/07/2016	10/08/2016	11/08/2016	19/10/2016	03/11/2016	18/11/2016	25/11/2016	30/11/2016	08/12/2016
02/09/2016	21/09/2016	22/09/2016	30/11/2016	15/12/2016	03/01/2017	06/01/2017	11/01/2017	19/01/2017
30/09/2016	19/10/2016	20/10/2016	23/12/2016	12/01/2017	27/01/2017	03/02/2017	08/02/2017	16/02/2017
26/10/2016	16/11/2016	17/11/2016	25/01/2017	09/02/2017	24/02/2017	03/03/2017	08/03/2017	16/03/2017
24/11/2016	13/12/2016	14/12/2016	21/02/2017	08/03/2017	23/03/2017	30/03/2017	04/04/2017	12/04/2017



Submission date	Validation of dossier completed	Start (day 1)	Rapporteur's AR	Co-rapporteur's comments	Comments from CVMP members including peer review	Draft list of questions	Rapporteur's meeting (teleconference)	Adoption of list of questions (day 120)
2017								
15/12/2016	12/01/2017	13/01/2017	23/03/2017	07/04/2017	21/04/2017	28/04/2017	04/05/2017	12/05/2017
27/01/2017	15/02/2017	16/02/2017	26/04/2017	11/05/2017	26/05/2017	02/06/2017	07/06/2017	15/06/2017
24/02/2017	15/03/2017	16/03/2017	24/05/2017	08/06/2017	23/06/2017	30/06/2017	05/07/2017	13/07/2017
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
19/04/2017	10/05/2017	11/05/2017	19/07/2017	03/08/2017	18/08/2017	25/08/2017	30/08/2017	07/09/2017
16/05/2017	07/06/2017	08/06/2017	16/08/2017	31/08/2017	15/09/2017	22/09/2017	27/09/2017	05/10/2017
23/06/2017	12/07/2017	13/07/2017	20/09/2017	05/10/2017	20/10/2017	27/10/2017	31/10/2017	09/11/2017
21/07/2017	09/08/2017	10/08/2017	18/10/2017	02/11/2017	17/11/2017	24/11/2017	29/11/2017	07/12/2017
01/09/2017	20/09/2017	21/09/2017	29/11/2017	14/12/2017	04/01/2018	08/01/2018	10/01/2018	18/01/2018
29/09/2017	18/10/2017	19/10/2017	22/12/2017	11/01/2018	26/01/2018	02/02/2018	07/02/2018	15/02/2018
24/10/2017	15/11/2017	16/11/2017	24/01/2018	08/02/2018	23/02/2018	02/03/2018	07/03/2018	15/03/2018
01/12/2017	20/12/2017	21/12/2017	28/02/2018	15/03/2018	28/03/2018	06/04/2018	11/04/2018	19/04/2018
2018								
08/01/2018	25/01/2018	26/01/2018	05/04/2018	20/04/2018	04/05/2018	11/05/2018	17/05/2018	25/05/2018
02/02/2018	21/02/2018	22/02/2018	02/05/2018	17/05/2018	01/06/2018	08/06/2018	13/06/2018	21/06/2018
02/03/2018	21/03/2018	22/03/2018	30/05/2018	14/06/2018	29/06/2018	06/07/2018	11/07/2018	19/07/2018
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
23/04/2018	16/05/2018	17/05/2018	25/07/2018	09/08/2018	24/08/2018	31/08/2018	05/09/2018	13/09/2018
25/05/2018	13/06/2018	14/06/2018	22/08/2018	06/09/2018	21/09/2018	28/09/2018	03/10/2018	11/10/2018
22/06/2018	11/07/2018	12/07/2018	19/09/2018	04/10/2018	19/10/2018	26/10/2018	31/10/2018	08/11/2018
20/07/2018	08/08/2018	09/08/2018	17/10/2018	01/11/2018	16/11/2018	23/11/2018	28/11/2018	06/12/2018

Responses to the list of questions (LoQ) - 2nd phase (60-day assessment after clock-stop for responses)

Submission of response to LoQ	Clock restart (day 121)	QRD comments	Joint AR on response to LoQ	CVMP & peer review comments	Rapporteur's meeting/ teleconference (if necessary)	Adoption of list of outstanding issues and decision on oral explanation (day 180)
2016						
07/10/2016	10/10/2016	28/10/2016	18/11/2016	28/11/2016	30/11/2016	08/12/2016
18/11/2016	21/11/2016	09/12/2016	03/01/2017	09/01/2017	11/01/2017	19/01/2017
16/12/2016	19/12/2016	06/01/2017	27/01/2017	06/02/2017	08/02/2017	16/02/2017
2017						
13/01/2017	16/01/2017	03/02/2017	24/02/2017	06/03/2017	08/03/2017	16/03/2017
10/02/2017	13/02/2017	03/03/2017	23/03/2017	03/04/2017	05/04/2017	12/04/2017
13/03/2017	14/03/2017	03/04/2017	21/04/2017	02/05/2017	04/05/2017	12/05/2017
12/04/2017	17/04/2017	05/05/2017	26/05/2017	05/06/2017	07/06/2017	15/06/2017
12/05/2017	15/05/2017	02/06/2017	23/06/2017	03/07/2017	05/07/2017	13/07/2017
N/A	N/A	N/A	N/A	N/A	N/A	N/A
07/07/2017	10/07/2017	28/07/2017	18/08/2017	28/08/2017	30/08/2017	07/09/2017
04/08/2017	07/08/2017	25/08/2017	15/09/2017	25/09/2017	27/09/2017	05/10/2017
08/09/2017	11/09/2017	29/09/2017	20/10/2017	30/10/2017	31/10/2017	09/11/2017
06/10/2017	09/10/2017	27/10/2017	17/11/2017	27/11/2017	29/11/2017	07/12/2017
17/11/2017	20/11/2017	08/12/2017	03/01/2018	08/01/2018	10/01/2018	18/01/2018
15/12/2017	18/12/2017	05/01/2018	26/01/2018	05/02/2018	07/02/2018	15/02/2018
2018						
12/01/2018	15/01/2018	02/02/2018	23/02/2018	05/03/2018	07/03/2018	15/03/2018
16/02/2018	19/02/2018	09/03/2018	30/03/2018	09/04/2018	11/04/2018	19/04/2018
26/03/2018	27/03/2018	16/04/2018	04/05/2018	15/05/2018	17/05/2018	25/05/2018
20/04/2018	23/04/2018	11/05/2018	01/06/2018	11/06/2018	13/06/2018	21/06/2018
18/05/2018	21/05/2018	08/06/2018	29/06/2018	09/07/2018	11/07/2018	19/07/2018

Submission of response to LoQ	Clock restart (day 121)	QRD comments	Joint AR on response to LoQ	CVMP & peer review comments	Rapporteur's meeting/ teleconference (if necessary)	Adoption of list of outstanding issues and decision on oral explanation (day 180)
N/A	N/A	N/A	N/A	N/A	N/A	N/A
13/07/2018	16/07/2018	03/08/2018	24/08/2018	03/09/2018	05/09/2018	13/09/2018
10/08/2018	13/08/2018	31/08/2018	21/09/2018	01/10/2018	03/10/2018	11/10/2018
07/09/2018	10/09/2018	28/09/2018	19/10/2018	29/10/2018	31/10/2018	08/11/2018
05/10/2018	08/10/2018	26/10/2018	16/11/2018	26/11/2018	28/11/2018	06/12/2018

Responses to the list of outstanding issues – 3rd phase (30-day assessment after clock-stop for outstanding issues or after oral explanation)

Submission date	Clock restart (day 181)	Joint AR	Draft CVMP AR	CVMP comments on joint AR	Adoption of opinion
2016					
08/11/2016	09/11/2016	18/11/2016	18/11/2016	25/11/2016	08/12/2016
N/A	N/A	N/A	N/A	N/A	N/A
2017					
17/01/2017	18/01/2017	27/01/2017	27/01/2017	03/02/2017	16/02/2017
14/02/2017	15/02/2017	24/02/2017	24/02/2017	03/03/2017	16/03/2017
13/03/2017	14/03/2017	23/03/2017	23/03/2017	30/03/2017	12/04/2017
12/04/2017	13/04/2017	21/04/2017	21/04/2017	28/04/2017	12/05/2017
16/05/2017	17/05/2017	26/05/2017	26/05/2017	02/06/2017	15/06/2017
13/06/2017	14/06/2017	23/06/2017	23/06/2017	30/06/2017	13/07/2017
N/A	N/A	N/A	N/A	N/A	N/A
08/08/2017	09/08/2017	18/08/2017	18/08/2017	25/08/2017	07/09/2017
05/09/2017	06/09/2017	15/09/2017	15/09/2017	22/09/2017	05/10/2017
10/10/2017	11/10/2017	20/10/2017	20/10/2017	27/10/2017	09/11/2017
07/11/2017	08/11/2017	17/11/2017	17/11/2017	24/11/2017	07/12/2017
N/A	N/A	N/A	N/A	N/A	N/A
2018					
16/01/2018	17/01/2018	26/01/2018	26/01/2018	02/02/2018	15/02/2018
13/02/2018	14/02/2018	23/02/2018	23/02/2018	02/03/2018	15/03/2018
20/03/2018	21/03/2018	28/03/2018	28/03/2018	06/04/2018	19/04/2018
25/04/2018	26/04/2018	04/05/2018	04/05/2018	11/05/2018	25/05/2018
22/05/2018	23/05/2018	01/06/2018	01/06/2018	08/06/2018	21/06/2018
19/06/2018	20/06/2018	29/06/2018	29/06/2018	06/07/2018	19/07/2018
N/A	N/A	N/A	N/A	N/A	N/A
14/08/2018	15/08/2018	24/08/2018	24/08/2018	31/08/2018	13/09/2018

Submission date	Clock restart (day 181)	Joint AR	Draft CVMP AR	CVMP comments on joint AR	Adoption of opinion
11/09/2018	12/09/2018	21/09/2018	21/09/2018	28/09/2018	11/10/2018
09/10/2018	10/10/2018	19/10/2018	19/10/2018	26/10/2018	08/11/2018
06/11/2018	07/11/2018	16/11/2018	16/11/2018	23/11/2018	06/12/2018

Responses to the list of questions (LoQ) further to the establishment of provisional MRLs - (90-day assessment after clock-stop for responses)

Submission date	Clock start (day 1)	CVMP rapporteur assessment report	Co-rapporteur critique	CVMP comments/ peer review	Adoption of opinion
2016					
09/09/2016	10/09/2016	24/10/2016	08/11/2016	18/11/2016	08/12/2016
21/10/2016	22/10/2016	05/12/2016	20/12/2016	30/12/2016	19/01/2017
18/11/2016	19/11/2016	02/01/2017	17/01/2017	27/01/2017	16/02/2017
16/12/2016	17/12/2016	30/01/2017	14/02/2017	24/02/2017	16/03/2017
2017					
12/01/2017	13/01/2017	27/02/2017	13/03/2017	23/03/2017	12/04/2017
10/02/2017	13/02/2017	28/03/2017	12/04/2017	21/04/2017	12/05/2017
17/03/2017	18/03/2017	01/05/2017	16/05/2017	26/05/2017	15/06/2017
14/04/2017	15/04/2017	29/05/2017	13/06/2017	23/06/2017	13/07/2017
N/A	N/A	N/A	N/A	N/A	N/A
09/06/2017	10/06/2017	24/07/2017	08/08/2017	18/08/2017	07/09/2017
07/07/2017	10/07/2017	21/08/2017	05/09/2017	15/09/2017	05/10/2017
11/08/2017	12/08/2017	25/09/2017	10/10/2017	20/10/2017	09/11/2017
08/09/2017	09/09/2017	23/10/2017	07/11/2017	17/11/2017	07/12/2017
20/10/2017	21/10/2017	04/12/2017	18/12/2017	22/12/2017	18/01/2018
17/11/2017	18/11/2017	01/01/2018	16/01/2018	26/01/2018	15/02/2018
15/12/2017	16/12/2017	29/01/2018	13/02/2018	23/02/2018	15/03/2018
2018					
19/01/2018	20/01/2018	05/03/2018	20/03/2018	28/03/2018	19/04/2018
23/02/2018	26/02/2018	10/04/2018	25/04/2018	04/05/2018	25/05/2018
23/03/2018	24/03/2018	07/05/2018	22/05/2018	01/06/2018	21/06/2018
20/04/2018	21/04/2018	04/06/2018	19/06/2018	29/06/2018	19/07/2018
N/A	N/A	N/A	N/A	N/A	N/A

Submission date	Clock start (day 1)	CVMP rapporteur assessment report	Co-rapporteur critique	CVMP comments/ peer review	Adoption of opinion
15/06/2018	16/06/2018	30/07/2018	14/08/2018	24/08/2018	13/09/2018
13/07/2018	14/07/2018	27/08/2018	11/09/2018	21/09/2018	11/10/2018
10/08/2018	11/08/2018	24/09/2018	09/10/2018	19/10/2018	08/11/2018
07/09/2018	08/09/2018	22/10/2018	06/11/2018	16/11/2018	06/12/2018

Type IB variations requiring linguistic review - 1st phase (30-day assessment)

Submission date	Validation of dossier completed	Start	Rapporteur AR	Notification of outcome
2017				
11/01/2017	19/01/2017	20/01/2017	08/02/2017	17/02/2017
08/02/2017	16/02/2017	17/02/2017	08/03/2017	17/03/2017
08/03/2017	16/03/2017	17/03/2017	05/04/2017	14/04/2017
04/04/2017	12/04/2017	13/04/2017	02/05/2017	12/05/2017
03/05/2017	12/05/2017	13/05/2017	01/06/2017	09/06/2017
07/06/2017	15/06/2017	16/06/2017	05/07/2017	14/07/2017
05/07/2017	13/07/2017	14/07/2017	02/08/2017	11/08/2017
N/A	N/A	N/A	N/A	N/A
30/08/2017	07/09/2017	08/09/2017	27/09/2017	06/10/2017
27/09/2017	05/10/2017	06/10/2017	24/10/2017	31/10/2017
27/10/2017	09/11/2017	10/11/2017	29/11/2017	08/12/2017
N/A	N/A	N/A	N/A	N/A
2018				
10/01/2018	18/01/2018	19/01/2018	07/02/2018	16/02/2018
07/02/2018	15/02/2018	16/02/2018	07/03/2018	16/03/2018
07/03/2018	15/03/2018	16/03/2018	04/04/2018	13/04/2018
11/04/2018	19/04/2018	20/04/2018	09/05/2018	18/05/2018
16/05/2018	25/05/2018	26/05/2018	14/06/2018	22/06/2018
13/06/2018	21/06/2018	22/06/2018	11/07/2018	20/07/2018
11/07/2018	19/07/2018	20/07/2018	08/08/2018	17/08/2018
N/A	N/A	N/A	N/A	N/A
05/09/2018	13/09/2018	14/09/2018	03/10/2018	12/10/2018
03/10/2018	11/10/2018	12/10/2018	31/10/2018	09/11/2018
29/10/2018	08/11/2018	09/11/2018	28/11/2018	07/12/2018

Renewals – 1st phase (90-day assessment)

Submission date	Validation of dossier completed	Start	Rapporteurs' AR	Co-rapporteur's comments	CVMP comments	Rapporteurs' revised AR	Adoption of opinion (or adoption of list of outstanding issues)
2016							
25/08/2016	09/09/2016	10/09/2016	24/10/2016	31/10/2016	14/11/2016	18/11/2016	08/12/2016
07/10/2016	21/10/2016	22/10/2016	05/12/2016	12/12/2016	23/12/2016	05/01/2017	19/01/2017
04/11/2016	18/11/2016	19/11/2016	03/01/2017	09/01/2017	23/01/2017	27/01/2017	16/02/2017
02/12/2016	16/12/2016	17/12/2016	30/01/2017	06/02/2017	20/02/2017	24/02/2017	16/03/2017
2017							
21/12/2016	12/01/2017	13/01/2017	27/02/2017	03/03/2017	17/03/2017	23/03/2017	12/04/2017
27/01/2017	11/02/2017	12/02/2017	28/03/2017	04/04/2017	18/04/2017	21/04/2017	12/05/2017
03/03/2017	17/03/2017	18/03/2017	01/05/2017	08/05/2017	22/05/2017	26/05/2017	15/06/2017
29/03/2017	14/04/2017	15/04/2017	29/05/2017	05/06/2017	19/06/2017	23/06/2017	13/07/2017
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
23/05/2017	09/06/2017	10/06/2017	24/07/2017	31/07/2017	14/08/2017	18/08/2017	07/09/2017
23/06/2017	07/07/2017	08/07/2017	21/08/2017	28/08/2017	11/09/2017	15/09/2017	05/10/2017
28/07/2017	11/08/2017	12/08/2017	25/09/2017	02/10/2017	16/10/2017	20/10/2017	09/11/2017
24/08/2017	08/09/2017	09/09/2017	23/10/2017	30/10/2017	13/11/2017	17/11/2017	07/12/2017
06/10/2017	20/10/2017	21/10/2017	04/12/2017	11/12/2017	22/12/2017	04/01/2018	18/01/2018
03/11/2017	17/11/2017	18/11/2017	04/01/2018	09/01/2018	22/01/2018	26/01/2018	15/02/2018
01/12/2017	15/12/2017	16/12/2017	29/01/2018	05/02/2018	19/02/2018	23/02/2018	15/03/2018
2018							
05/01/2018	19/01/2018	20/01/2018	05/03/2018	12/03/2018	23/03/2018	28/03/2018	19/04/2018
09/02/2018	25/02/2018	26/02/2018	10/04/2018	17/04/2018	01/05/2018	04/05/2018	25/05/2018
09/03/2018	23/03/2018	24/03/2018	07/05/2018	14/05/2018	28/05/2018	01/06/2018	21/06/2018
06/04/2018	20/04/2018	21/04/2018	04/06/2018	11/06/2018	25/06/2018	29/06/2018	19/07/2018
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
01/06/2018	15/06/2018	16/06/2018	30/07/2018	06/08/2018	20/08/2018	24/08/2018	13/09/2018
29/06/2018	13/07/2018	14/07/2018	27/08/2018	03/09/2018	17/09/2018	21/09/2018	11/10/2018

Submission date	Validation of dossier completed	Start	Rapporteurs' AR	Co-rapporteur's comments	CVMP comments	Rapporteurs' revised AR	Adoption of opinion (or adoption of list of outstanding issues)
27/07/2018	10/08/2018	11/08/2018	24/09/2018	01/10/2018	15/10/2018	19/10/2018	08/11/2018
23/08/2018	07/09/2018	08/09/2018	22/10/2018	29/10/2018	12/11/2018	16/11/2018	06/12/2018

Renewals - 2nd phase (30-day assessment after request for supplementary information)

Submission of responses to RSI	Start	Rapporteurs' AR on responses	Adoption of opinion
2017			
30/01/2017	30/01/2017	06/02/2017	16/02/2017
27/02/2017	27/02/2017	06/03/2017	16/03/2017
27/03/2017	27/03/2017	03/04/2017	12/04/2017
24/04/2017	24/04/2017	02/05/2017	12/05/2017
22/05/2017	23/05/2017	05/06/2017	15/06/2017
26/06/2017	26/06/2017	03/07/2017	13/07/2017
N/A	N/A	N/A	N/A
18/08/2017	19/08/2017	28/08/2017	07/09/2017
18/09/2017	18/09/2017	25/09/2017	05/10/2017
16/10/2017	17/10/2017	30/10/2017	09/11/2017
20/11/2017	20/11/2017	27/11/2017	07/12/2017
N/A	N/A	N/A	N/A
2018			
26/01/2018	26/01/2018	05/02/2018	15/02/2018
23/02/2018	23/02/2018	05/03/2018	15/03/2018
26/03/2018	26/03/2018	06/04/2018	19/04/2018
30/04/2018	30/04/2018	15/05/2018	25/05/2018
01/06/2018	01/06/2018	11/06/2018	21/06/2018
29/06/2018	29/06/2018	09/07/2018	19/07/2018
N/A	N/A	N/A	N/A
23/08/2018	23/08/2018	03/09/2018	13/09/2018
21/09/2018	21/09/2018	01/10/2018	11/10/2018
19/10/2018	19/10/2018	29/10/2018	08/11/2018
16/11/2018	16/11/2018	26/11/2018	06/12/2018
N/A	N/A	N/A	N/A

Type II variations – 1st phase (90-day assessment)

Submission date	Validation of dossier completed	Start	Rapporteurs' AR	Co-rapporteur's comments	CVMP comments	Rapporteurs' revised AR	Adoption of opinion (or adoption of list of outstanding issues)
2016							
25/08/2016	09/09/2016	10/09/2016	24/10/2016	31/10/2016	14/11/2016	18/11/2016	08/12/2016
07/10/2016	21/10/2016	22/10/2016	05/12/2016	12/12/2016	23/12/2016	05/01/2017	19/01/2017
04/11/2016	18/11/2016	19/11/2016	03/01/2017	09/01/2017	23/01/2017	27/01/2017	16/02/2017
02/12/2016	16/12/2016	17/12/2016	30/01/2017	06/02/2017	20/02/2017	24/02/2017	16/03/2017
21/12/2016	12/01/2017	13/01/2017	27/02/2017	03/03/2017	17/03/2017	23/03/2017	12/04/2017
2017							
21/12/2016	12/01/2017	13/01/2017	27/02/2017	03/03/2017	17/03/2017	23/03/2017	12/04/2017
27/01/2017	11/02/2017	12/02/2017	28/03/2017	04/04/2017	18/04/2017	21/04/2017	12/05/2017
03/03/2017	17/03/2017	18/03/2017	01/05/2017	08/05/2017	22/05/2017	26/05/2017	15/06/2017
29/03/2017	14/04/2017	15/04/2017	29/05/2017	05/06/2017	19/06/2017	23/06/2017	13/07/2017
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
23/05/2017	09/06/2017	10/06/2017	24/07/2017	31/07/2017	14/08/2017	18/08/2017	07/09/2017
23/06/2017	07/07/2017	08/07/2017	21/08/2017	28/08/2017	11/09/2017	15/09/2017	05/10/2017
28/07/2017	11/08/2017	12/08/2017	25/09/2017	02/10/2017	16/10/2017	20/10/2017	09/11/2017
24/08/2017	08/09/2017	09/09/2017	23/10/2017	30/10/2017	13/11/2017	17/11/2017	07/12/2017
06/10/2017	20/10/2017	21/10/2017	04/12/2017	11/12/2017	22/12/2017	04/01/2018	18/01/2018
03/11/2017	17/11/2017	18/11/2017	04/01/2018	09/01/2018	22/01/2018	26/01/2018	15/02/2018
01/12/2017	15/12/2017	16/12/2017	29/01/2018	05/02/2018	19/02/2018	23/02/2018	15/03/2018
2018							
05/01/2018	19/01/2018	20/01/2018	05/03/2018	12/03/2018	23/03/2018	28/03/2018	19/04/2018
12/02/2018	25/02/2018	26/02/2018	10/04/2018	17/04/2018	01/05/2018	04/05/2018	25/05/2018
09/03/2018	23/03/2018	24/03/2018	07/05/2018	14/05/2018	28/05/2018	01/06/2018	21/06/2018
06/04/2018	20/04/2018	21/04/2018	04/06/2018	11/06/2018	25/06/2018	29/06/2018	19/07/2018
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Submission date	Validation of dossier completed	Start	Rapporteurs' AR	Co-rapporteur's comments	CVMP comments	Rapporteurs' revised AR	Adoption of opinion (or adoption of list of outstanding issues)
01/06/2018	15/06/2018	16/06/2018	30/07/2018	06/08/2018	20/08/2018	24/08/2018	13/09/2018
29/06/2018	13/07/2018	14/07/2018	27/08/2018	03/09/2018	17/09/2018	21/09/2018	11/10/2018
27/07/2018	10/08/2018	11/08/2018	24/09/2018	01/10/2018	15/10/2018	19/10/2018	08/11/2018
23/08/2018	07/09/2018	08/09/2018	22/10/2018	29/10/2018	12/11/2018	16/11/2018	06/12/2018

Type II variations, type IB worksharing applications and annual reassessments - 1st phase (60-day assessment)

Submission date	Validation of dossier completed	Start	Rapporteurs' AR	Co-rapporteur's comments	Rapporteur's revised AR	Adoption of opinion (or adoption of list of outstanding issues)
2016						
26/09/2016	10/10/2016	11/10/2016	09/11/2016	18/11/2016	25/11/2016	08/12/2016
07/11/2016	21/11/2016	22/11/2016	21/12/2016	03/01/2017	06/01/2017	19/01/2017
05/12/2016	19/12/2016	20/12/2016	18/01/2017	27/01/2017	03/02/2017	16/02/2017
2017						
02/01/2017	16/01/2017	17/01/2017	15/02/2017	24/02/2017	03/03/2017	16/03/2017
30/01/2017	13/02/2017	13/02/2017	14/03/2017	23/03/2017	30/03/2017	12/04/2017
28/02/2017	14/03/2017	15/03/2017	13/04/2017	21/04/2017	28/04/2017	12/05/2017
29/03/2017	17/04/2017	18/04/2017	17/05/2017	26/05/2017	02/06/2017	15/06/2017
27/04/2017	15/05/2017	16/05/2017	14/06/2017	23/06/2017	30/06/2017	13/07/2017
N/A	N/A	N/A	N/A	N/A	N/A	N/A
26/06/2017	10/07/2017	11/07/2017	09/08/2017	18/08/2017	25/08/2017	07/09/2017
24/07/2017	07/08/2017	08/08/2017	06/09/2017	15/09/2017	22/09/2017	05/10/2017
25/08/2017	11/09/2017	12/09/2017	11/10/2017	20/10/2017	27/10/2017	09/11/2017
25/09/2017	09/10/2017	10/10/2017	08/11/2017	17/11/2017	24/11/2017	07/12/2017
06/11/2017	20/11/2017	21/11/2017	20/12/2017	04/01/2018	08/01/2018	18/01/2018
04/12/2017	18/12/2017	19/12/2017	17/01/2018	26/01/2018	02/02/2018	15/02/2018
21/12/2017	15/01/2018	16/01/2018	14/02/2018	23/02/2018	02/03/2018	15/03/2018
2018						
05/02/2018	19/02/2018	20/02/2018	21/03/2018	28/03/2018	06/04/2018	19/04/2018
13/03/2018	27/03/2018	28/03/2018	26/04/2018	04/05/2018	11/05/2018	25/05/2018
09/04/2018	23/04/2018	24/04/2018	23/05/2018	01/06/2018	08/06/2018	21/06/2018
02/05/2018	22/05/2018	22/05/2018	20/06/2018	29/06/2018	06/07/2018	19/07/2018
N/A	N/A	N/A	N/A	N/A	N/A	N/A

Submission date	Validation of dossier completed	Start	Rapporteurs' AR	Co-rapporteur's comments	Rapporteur's revised AR	Adoption of opinion (or adoption of list of outstanding issues)
02/07/2018	16/07/2018	17/07/2018	15/08/2018	24/08/2018	31/08/2018	13/09/2018
30/07/2018	13/08/2018	14/08/2018	12/09/2018	21/09/2018	28/09/2018	11/10/2018
24/08/2018	10/09/2018	11/09/2018	10/10/2018	19/10/2018	26/10/2018	08/11/2018
24/09/2018	08/10/2018	09/10/2018	07/11/2018	16/11/2018	23/11/2018	06/12/2018

Type II variations – 1st phase (30-day assessment)

Submission date	Validation of dossier completed	Start	Rapporteurs' AR	Co-rapporteur's comments	Rapporteur's revised AR	Adoption of opinion (or adoption of list of outstanding issues)
2016						
26/10/2016	08/11/2016	09/11/2016	23/11/2016	28/11/2016	02/12/2016	08/12/2016
N/A	N/A	N/A	N/A	N/A	N/A	N/A
2017						
06/01/2017	17/01/2017	18/01/2017	01/02/2017	06/02/2017	10/02/2017	16/02/2017
03/02/2017	14/02/2017	15/02/2017	01/03/2017	06/03/2017	10/03/2017	16/03/2017
02/03/2017	13/03/2017	14/03/2017	28/03/2017	31/03/2017	06/04/2017	12/04/2017
03/04/2017	12/04/2017	13/04/2017	27/04/2017	02/05/2017	05/05/2017	12/05/2017
04/04/2017	16/05/2017	17/05/2017	31/05/2017	05/06/2017	09/06/2017	15/06/2017
01/06/2017	13/06/2017	14/06/2017	28/06/2017	03/07/2017	07/07/2017	13/07/2017
N/A	N/A	N/A	N/A	N/A	N/A	N/A
28/07/2017	08/08/2017	09/08/2017	23/08/2017	28/08/2017	01/09/2017	07/09/2017
24/08/2017	05/09/2017	06/09/2017	20/09/2017	25/09/2017	29/09/2017	05/10/2017
29/09/2017	10/10/2017	11/10/2017	25/10/2017	30/10/2017	03/11/2017	09/11/2017
25/10/2017	07/11/2017	08/11/2017	22/11/2017	27/11/2017	01/12/2017	07/12/2017
N/A	N/A	N/A	N/A	N/A	N/A	N/A
2018						
08/01/2018	16/01/2018	17/01/2018	31/01/2018	05/02/2018	09/02/2018	15/02/2018
05/02/2018	13/02/2018	14/02/2018	28/02/2018	05/03/2018	09/03/2018	15/03/2018
12/03/2018	20/03/2018	21/03/2018	04/04/2018	09/04/2018	13/04/2018	19/04/2018
17/04/2018	25/04/2018	26/04/2018	10/05/2018	15/05/2018	18/05/2018	25/05/2018
08/05/2018	22/05/2018	23/05/2018	06/06/2018	11/06/2018	15/06/2018	21/06/2018
11/06/2018	19/06/2018	20/06/2018	04/07/2018	09/07/2018	13/07/2018	19/07/2018
N/A	N/A	N/A	N/A	N/A	N/A	N/A
06/08/2018	14/08/2018	15/08/2018	29/08/2018	03/09/2018	07/09/2018	13/09/2018

Submission date	Validation of dossier completed	Start	Rapporteurs' AR	Co-rapporteur's comments	Rapporteur's revised AR	Adoption of opinion (or adoption of list of outstanding issues)
03/09/2018	11/09/2018	12/09/2018	26/09/2018	01/10/2018	05/10/2018	11/10/2018
01/10/2018	09/10/2018	10/10/2018	24/10/2018	29/10/2018	02/11/2018	08/11/2018
25/10/2018	06/11/2018	07/11/2018	21/11/2018	26/11/2018	30/11/2018	06/12/2018
N/A	N/A	N/A	N/A	N/A	N/A	N/A

Response to the request for supplementary information for type II variations, annual reassessments and type IB worksharing applications – 2nd phase (60-day assessment)

Submission of responses	Start	Rapporteurs' AR	CVMP comments	Rapporteur's revised AR	Adoption of opinion
2016					
07/10/2016	10/10/2016	28/10/2016	08/11/2016	18/11/2016	08/12/2016
18/11/2016	21/11/2016	09/12/2016	20/12/2016	04/01/2017	19/01/2017
16/12/2016	19/12/2016	10/01/2017	17/01/2017	27/01/2017	16/02/2017
2017					
13/01/2017	16/01/2017	03/02/2017	14/02/2017	24/02/2017	16/03/2017
10/02/2017	13/02/2017	02/03/2017	13/03/2017	23/03/2017	12/04/2017
13/03/2017	14/03/2017	31/03/2017	12/04/2017	21/04/2017	12/05/2017
12/04/2017	17/04/2017	05/05/2017	16/05/2017	26/05/2017	15/06/2017
12/05/2017	15/05/2017	02/06/2017	13/06/2017	23/06/2017	13/07/2017
N/A	N/A	N/A	N/A	N/A	N/A
07/07/2017	10/07/2017	28/07/2017	08/08/2017	18/08/2017	07/09/2017
04/08/2017	07/08/2017	25/08/2017	05/09/2017	15/09/2017	05/10/2017
08/09/2017	11/09/2017	29/09/2017	10/10/2017	20/10/2017	09/11/2017
06/10/2017	09/10/2017	27/10/2017	07/11/2017	17/11/2017	07/12/2017
17/11/2017	20/11/2017	08/12/2017	19/12/2017	04/01/2018	18/01/2018
15/12/2017	18/12/2017	05/01/2018	16/01/2018	26/01/2018	15/02/2018
2018					
12/01/2018	15/01/2018	02/02/2018	13/02/2018	23/02/2018	15/03/2018
16/02/2018	19/02/2018	09/03/2018	20/03/2018	28/03/2018	19/04/2018
26/03/2018	27/03/2018	13/04/2018	25/04/2018	04/05/2018	25/05/2018
20/04/2018	23/04/2018	11/05/2018	22/05/2018	01/06/2018	21/06/2018
18/05/2018	21/05/2018	08/06/2018	19/06/2018	29/06/2018	19/07/2018
N/A	N/A	N/A	N/A	N/A	N/A
13/07/2018	16/07/2018	03/08/2018	14/08/2018	24/08/2018	13/09/2018
10/08/2018	13/08/2018	31/08/2018	11/09/2018	21/09/2018	11/10/2018

Submission of responses	Start	Rapporteurs' AR	CVMP comments	Rapporteur's revised AR	Adoption of opinion
07/09/2018	10/09/2018	28/09/2018	09/10/2018	19/10/2018	08/11/2018
05/10/2018	08/10/2018	26/10/2018	06/11/2018	16/11/2018	06/12/2018

Response to the request for supplementary information for type II variations, annual reassessments and type IB worksharing applications – 2nd phase (30-day assessment)

Submission of responses	Start	Rapporteurs' AR	CVMP comments	Rapporteur's revised AR	Adoption of opinion
2016					
08/11/2016	09/11/2016	23/11/2016	28/11/2016	02/12/2016	08/12/2016
N/A	N/A	N/A	N/A	N/A	N/A
2017					
17/01/2017	18/01/2017	01/02/2017	06/02/2017	10/02/2017	16/02/2017
14/02/2017	15/02/2017	01/03/2017	06/03/2017	10/03/2017	16/03/2017
13/03/2017	14/03/2017	28/03/2017	31/03/2017	06/04/2017	12/04/2017
10/03/2017	13/04/2017	27/04/2017	02/05/2017	05/05/2017	12/05/2017
16/05/2017	17/05/2017	31/05/2017	05/06/2017	09/06/2017	15/06/2017
13/06/2017	14/06/2017	28/06/2017	03/07/2017	07/07/2017	13/07/2017
N/A	N/A	N/A	N/A	N/A	N/A
08/08/2017	09/08/2017	23/08/2017	28/08/2017	01/09/2017	07/09/2017
05/09/2017	06/09/2017	20/09/2017	25/09/2017	29/09/2017	05/10/2017
10/10/2017	11/10/2017	25/10/2017	30/10/2017	03/11/2017	09/11/2017
07/11/2017	08/11/2017	22/11/2017	27/11/2017	01/12/2017	07/12/2017
N/A	N/A	N/A	N/A	N/A	N/A
2018					
16/01/2018	17/01/2018	31/01/2018	05/02/2018	09/02/2018	15/02/2018
13/02/2018	14/02/2018	28/02/2018	05/03/2018	09/03/2018	15/03/2018
20/03/2018	21/03/2018	04/04/2018	09/04/2018	13/04/2018	19/04/2018
25/04/2018	26/04/2018	10/05/2018	15/05/2018	18/05/2018	25/05/2018
22/05/2018	23/05/2018	06/06/2018	11/06/2018	15/06/2018	21/06/2018
19/06/2018	20/06/2018	04/07/2018	09/07/2018	13/07/2018	19/07/2018
N/A	N/A	N/A	N/A	N/A	N/A
14/08/2018	15/08/2018	29/08/2018	03/09/2018	07/09/2018	13/09/2018
11/09/2018	12/09/2018	26/09/2018	01/10/2018	05/10/2018	11/10/2018

Submission of responses	Start	Rapporteurs' AR	CVMP comments	Rapporteur's revised AR	Adoption of opinion
09/10/2018	10/10/2018	24/10/2018	29/10/2018	02/11/2018	08/11/2018
06/11/2018	07/11/2018	21/11/2018	26/11/2018	30/11/2018	06/12/2018
N/A	N/A	N/A	N/A	N/A	N/A