



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 February 2018
EMA/426724/2014 Rev. 3
Product Development Scientific Support Department

Dates of 2018 SAWP meetings and submission deadlines

Scientific advice, protocol assistance, qualification of biomarkers and parallel consultation EMA/EUnetHTA requests

SAWP Meeting dates 2018	
1 st meeting	8 January – 11 January 2018
2 nd meeting	5 February – 8 February 2018
3 rd meeting	5 March – 8 March 2018
4 th meeting	9 April – 12 April 2018
5 th meeting	14 May – 17 May 2018
6 th meeting	11 June – 14 June 2018
7 th meeting	9 July – 12 July 2018
8 th meeting	3 – 6 September 2018
9 th meeting	1 – 4 October 2018
10 th meeting	29 – 31 October 2018
11 th meeting	26 – 29 November 2018

Letter of intent latest template:

http://www.ema.europa.eu/docs/en_GB/document_library/Template_or_form/2009/11/WC500011910.pdf



2018 Submission deadlines - Scientific advice, protocol assistance, qualification of biomarkers

Presubmission phase					Evaluation phase					
Start of procedure	Presubmission meeting			Final briefing package by	SAWP1	SAWP2	D40	SAWP3	D70	PRAC endorsement
	Yes		No		Start of procedure	Reports discussed	CHMP Adoption	Discussion Meeting (if required)	CHMP adoption	(PASS procedures only)
	Letter of Intent and draft briefing package by	Dates of presubmission meeting	Letter of Intent and draft briefing package by							
8 – 11 Jan 18	6 Nov 17	13 Nov 17 – 22 Dec 17	8 Dec 17	3 Jan 18	8 – 11 Jan 18	5 – 8 Feb 18	19 – 22 Feb 18	5 – 8 Mar 18	19 – 22 Mar 18	9 – 12 Apr 18
5 – 8 Feb 18	8 Dec 17	15 Dec 17 – 26 Jan 18	12 Jan 18	31 Jan 18	5 – 8 Feb 18	5 – 8 Mar 18	19 – 22 Mar 18	9 – 12 Apr 18	23 – 26 Apr 18	14 – 17 May 18
5 – 8 Mar 18	12 Jan 18	19 Jan 18 – 23 Feb 18	9 Feb 18	28 Feb 18	5 – 8 Mar 18	9 – 12 Apr 18	23 – 26 Apr 18	14 – 17 May 18	28 – 31 May 18	11 – 14 Jun 18
9 – 12 Apr 18	9 Feb 18	16 Feb 18 – 28 Mar 18	16 Mar 18	4 Apr 18	9 – 12 Apr 18	14 – 17 May 18	28 – 31 May 18	11 – 14 Jun 18	25 – 28 Jun 18	9 – 12 Jul 18
14 – 17 May 18	16 Mar 18	23 Mar 18 – 3 May 18	16 Apr 18	8 May 18	14 – 17 May 18	11 – 14 Jun 18	25 – 28 Jun 18	9 – 12 Jul 18	23 – 26 Jul 18	3 – 6 Sep 18
11 – 14 Jun 18	13 Apr 18	23 Apr 18 – 1 Jun 18	18 May 18	6 Jun 18	11 – 14 Jun 18	9 – 12 Jul 18	23 – 26 Jul 18	3 – 6 Sep 18	17 – 20 Sep 18	1 – 4 Oct 18
9 – 12 Jul 18	18 May 18	25 May 18 – 29 Jun 18	15 Jun 18	4 Jul 18	9 – 12 Jul 18	3 – 6 Sep 18	17 – 20 Sep 18	1 – 4 Oct 18	15 – 18 Oct 18	29 – 31 Oct 18
3 – 6 Sep 18	15 Jun 18	22 Jun 18 – 24 Aug 18	10 Aug 18	29 Aug 18	3 – 6 Sep 18	1 – 4 Oct 18	15 – 18 Oct 18	29 – 31 Oct 18	12 – 15 Nov 18	26 – 29 Nov 18
1 – 4 Oct 18	10 Aug 18	17 Aug 18 – 21 Sep 18	7 Sep 18	26 Sep 18	1 – 4 Oct 18	29 – 31 Oct 18	12 – 15 Nov 18	26 – 29 Nov 18	10 – 13 Dec 18	14 – 17 Jan 19
29 – 31 Oct 18	7 Sep 18	14 Sep 18 – 19 Oct 18	5 Oct 18	24 Oct 18	29 – 31 Oct 18	26 – 29 Nov 18	10 – 13 Dec 18	14 – 17 Jan 19	28 – 31 Jan 19	11 – 14 Feb 19
26 – 29 Nov 18	5 Oct 18	12 Oct 18 – 16 Nov 18	5 Nov 18	21 Nov 18	26 – 29 Nov 18	14 – 17 Jan 19	28 – 31 Jan 19	11 – 14 Feb 19	25 – 28 Feb 19	11 – 14 Mar 19

2018 Submission deadlines – Parallel consultation EMA/EUnetHTA

Start of procedure	Simultaneous notification	Presubmission phase			Evaluation phase				
	Letter of Intent by	Presubmission meeting		Final briefing package by	SAWP 1	Pre face to face teleconference (closed: regulators with HTAs only)	SAWP 3	D70	D75 ¹
		Yes (exceptionally)	No (default)		Start of procedure		Face to face meeting (applicant, regulators and HTAs)	CHMP adoption	EUnetHTA / HTAB final recommendation letter
		Draft briefing package by	Draft briefing package by						
8 – 11 Jan 18	6 Nov 17	6 Nov 17	8 Dec 17	3 Jan 18	8 – 11 Jan 18	12 – 13 Feb 18	5 – 8 Mar 18	19 – 22 Mar 18	26 – 29 Mar 18
5 – 8 Feb 18	8 Dec 17	8 Dec 17	5 Jan 18	31 Jan 18	5 – 8 Feb 18	12 – 13 Mar 18	9 – 12 Apr 18	23 – 26 Apr 18	Apr 30 – May 4 18
5 – 8 Mar 18	12 Jan 18	12 Jan 18	2 Feb 18	28 Feb 18	5 – 8 Mar 18	16 – 17 Apr 18	14 – 17 May 18	28 – 31 May 18	4 – 7 Jun 18
9 – 12 Apr 18	9 Feb 18	9 Feb 18	9 Mar 18	4 Apr 18	9 – 12 Apr 18	22 – 23 May 18	11 – 14 Jun 18	25 – 28 Jun 18	2 – 6 Jul 18
14 – 17 May 18	16 Mar 18	16 Mar 18	13 Apr 18	8 May 18	14 – 17 May 18	18 – 19 Jun 18	9 – 12 Jul 18	23 – 26 Jul 18	Jul 30 – Aug 3 18
11 – 14 Jun 18	13 Apr 18	13 Apr 18	11 May 18	6 Jun 18	11 – 14 Jun 18	16 – 17 Jul 18	3 – 6 Sep 18	17 – 20 Sep 18	24 – 28 Sep 18
9 – 12 Jul 18	18 May 18	18 May 18	8 Jun 18	4 Jul 18	9 – 12 Jul 18	10 – 11 Sep 18	1 – 4 Oct 18	15 – 18 Oct 18	22 – 26 Oct 18
3 – 6 Sep 18	15 Jun 18	15 Jun 18	3 Aug 18	29 Aug 18	3 – 6 Sep 18	8 – 9 Oct 18	29 – 31 Oct 18	12 – 15 Nov 18	19 – 23 Nov 18
1 – 4 Oct 18	10 Aug 18	10 Aug 18	31 Aug 18	26 Sep 18	1 – 4 Oct 18	5 – 6 Nov 18	26 – 29 Nov 18	10 – 13 Dec 18	17 – 21 Dec 18
29 – 31 Oct 18	7 Sep 18	7 Sep 18	28 Sep 18	24 Oct 18	29 – 31 Oct 18	3 – 4 Dec 18	14 – 17 Jan 19	28 – 31 Jan 19	4 – 8 Feb 19
26 – 29 Nov 18	5 Oct 18	5 Oct 18	26 Oct 18	21 Nov 18	26 – 29 Nov 18	21 – 22 Jan 19	11 – 14 Feb 19	25 – 28 Feb 19	4 – 8 Mar 19

¹ This deadline pertains to PCC procedures only. For PCI procedures, this deadline could vary due to different national-level procedures.