



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

6 August 2019
EMA/444927/2017 Rev.1
Product Development Scientific Support Department

Dates of 2019 SAWP meetings and submission deadlines

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

SAWP Meeting dates 2019	
1 st meeting	14 January – 17 January 2019
2 nd meeting	11 February – 14 February 2019
3 rd meeting	12 March – 15 March 2019*
4 th meeting	8 April – 11 April 2019
5 th meeting	13 May – 16 May 2019
6 th meeting	11 June – 14 June 2019*
7 th meeting	8 July – 11 July 2019
8 th meeting	2 – 5 September 2019
9 th meeting	30 September – 3 October 2019
10 th meeting	28 – 31 October 2019
11 th meeting	25 – 28 November 2019

Please note that from March 2019 SAWP plenary meetings will be held in the new Agency's headquarters in Amsterdam, The Netherlands.

Letter of intent latest template:

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

*Tuesday start

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2019 Submission deadlines - Scientific advice, protocol assistance, qualification of biomarkers

Presubmission phase					Evaluation phase					
Start of procedure	Presubmission meeting**			Revised briefing document by	SAWP1	SAWP2	D40	SAWP3	D70	PRAC endorsement (PASS procedures only)
	Yes		No		Start of procedure	Reports discussed	CHMP Adoption	Discussion Meeting (if required)	CHMP adoption	
	Letter of Intent and draft briefing document by	Dates of presubmission meeting	Letter of Intent and draft briefing document by							
14 – 17 Jan 19	5 Nov 18	12 Nov 18 – 4 Jan 19	7 Dec 18	9 Jan 19	14 – 17 Jan 19	11 – 14 Feb 19	25 – 28 Feb 19	12 – 15 Mar 19	25 – 28 Mar 19	8 – 11 Apr 19
11 – 14 Feb 19	7 Dec 18	17 Dec 18 – 1 Feb 19	18 Jan 19	6 Feb 19	11 – 14 Feb 19	12 – 15 Mar 19	25 – 28 Mar 19	8 – 11 Apr 19	23 – 26 Apr 19	13 – 16 May 19
12 – 15 Mar 19	18 Jan 19	28 Jan 19 – 1 Mar 19	15 Feb 19	6 Mar 19	12 – 15 Mar 19	8 – 11 Apr 19	23 – 26 Apr 19	13 – 16 May 19	27 – 29 May 19	11 – 14 Jun 19
8 – 11 Apr 19	15 Feb 19	25 Feb 19 – 29 Mar 19	15 Mar 19	3 Apr 19	8 – 11 Apr 19	13 – 16 May 19	27 – 29 May 19	11 – 14 Jun 19	24 – 27 Jun 19	8 – 11 Jul 19
13 – 16 May 19	15 Mar 19	25 Mar 19 – 3 May 19	17 Apr 19	8 May 19	13 – 16 May 19	11 – 14 Jun 19	24 – 27 Jun 19	8 – 11 Jul 19	22 – 25 Jul 19	2 – 5 Sep 19
11 – 14 Jun 19	17 Apr 19	27 Apr 19 – 31 May 19	17 May 19	5 Jun 19	11 – 14 Jun 19	8 – 11 Jul 19	22 – 25 Jul 19	2 – 5 Sep 19	16 – 19 Sep 19	30 Sep – 3 Oct 19
8 – 11 Jul 19	17 May 19	27 May 19 – 28 Jun 19	14 Jun 19	3 Jul 19	8 – 11 Jul 19	2 – 5 Sep 19	16 – 19 Sep 19	30 Sep – 3 Oct 19	14 – 17 Oct 19	28 – 31 Oct 19
2 – 5 Sep 19	14 Jun 19	24 Jun 19 – 23 Aug 19	9 Aug 19	28 Aug 19	2 – 5 Sep 19	30 Sep – 3 Oct 19	14 – 17 Oct 19	28 – 31 Oct 19	11 – 14 Nov 19	25 – 28 Nov 19
30 Sep – 3 Oct 19	9 Aug 19	19 Aug 19 – 20 Sep 19	6 Sep 19	25 Sep 19	30 Sep – 3 Oct 19	28 – 31 Oct 19	11 – 14 Nov 19	25 – 28 Nov 19	9 – 12 Dec 19	13 – 16 Jan 20
28 – 31 Oct 19	6 Sep 19	16 Sep 19 – 18 Oct 19	4 Oct 19	23 Oct 19	28 – 31 Oct 19	25 – 28 Nov 19	9 – 12 Dec 19	13 – 16 Jan 20	27 – 30 Jan 20	10 – 13 Feb 20
25 – 28 Nov 19	4 Oct 19	14 Oct 19 – 15 Nov 19	4 Nov 19	20 Nov 19	25 – 28 Nov 19	13 – 16 Jan 20	27 – 30 Jan 20	10 – 13 Feb 20	24 – 27 Feb 20	9 – 12 Mar 20

** Please note that from September 2018 presubmission meetings for Scientific Advice procedures will only be held via teleconference due to the relocation of the EMA to Amsterdam, The Netherlands.

2019 Submission deadlines – Parallel consultation EMA/EUnetHTA

Start of procedure	Simultaneous notification		Presubmission phase			Evaluation phase					
	Letter of Intent by	Presubmission meeting		Written requests for clarification EUnetHTA	Revised briefing document by	SAWP 1 Start of procedure	Pre face to face teleconference (closed: regulators with HTAs only)	Written answers by applicant	SAWP 3	D70	D75 ¹
		Yes (exceptionally)	No (default)						Face to face meeting (<i>applicant, regulators and HTAs</i>)	CHMP adoption	EUnetHTA / HTAB final recommendation letter
Draft briefing document by	Draft briefing document by										
14 – 17 Jan 19	5 Nov 18	5 Nov 18	7 Dec 18	21 Dec 18	9 Jan 19	14 – 17 Jan 19	18 – 19 Feb 19	4 Mar 19	12 – 15 Mar 19	25 – 28 Mar 19	29 Mar 19
11 – 14 Feb 19	7 Dec 18	7 Dec 18	18 Jan 19	1 Feb 19	6 Feb 19	11 – 14 Feb 19	18 – 19 Mar 19	1 Apr 19	8 – 11 Apr 19	23 – 26 Apr 19	29 Apr 19
12 – 15 Mar 19	18 Jan 19	18 Jan 19	15 Feb 19	1 Mar 19	6 Mar 19	12 – 15 Mar 19	15 – 16 Apr 19	4 May 19	13 – 16 May 19	27 – 29 May 19	3 Jun 19
8 – 11 Apr 19	15 Feb 19	15 Feb 19	15 Mar 19	29 Mar 19	3 Apr 19	8 – 11 Apr 19	20 -21May 19	1 Jun 19	11 – 14 Jun 19	24 – 27 Jun 19	28 Jun 19
13 – 16 May 19	15 Mar 19	15 Mar 19	17 Apr 19	2 May 19	8 May 19	13 – 16 May 19	17 – 18 Jun 19	27 Jun 19	8 – 11 Jul 19	22 – 25 Jul 19	26 Jul 19
11 – 14 Jun 19	17 Apr 19	17 Apr 19	17 May 19	29 May 19	5 Jun 19	11 – 14 Jun 19	15 – 16 Jul 19	24 Aug 19	2 – 5 Sep 19	16 – 19 Sep 19	20 Sep 19
8 – 11 Jul 19	17 May 19	17 May 19	14 Jun 19	28 Jun 19	3 Jul 19	8 – 11 Jul 19	9 – 10 Sep 19	21 Sep 19	30 Sep – 3 Oct 19	14 – 17 Oct 19	18 Oct 19
2 – 5 Sep 19	14 Jun 19	14 Jun 19	9 Aug 19	23 Aug 19	28 Aug 19	2 – 5 Sep 19	7 – 8 Oct 19	19 Oct 19	28 – 31 Oct 19	11 – 14 Nov 19	18 Nov 19
30 Sep – 3 Oct 19	9 Aug 19	9 Aug 19	6 Sep 19	20 Sep 19	25 Sep 19	30 Sep – 3 Oct 19	4 – 5 Nov 19	17 Nov 19	25 – 28 Nov 19	9 – 12 Dec 19	13 Dec 19
28 – 31 Oct 19	6 Sep 19	6 Sep 19	4 Oct 19	18 Oct 19	23 Oct 19	28 – 31 Oct 19	4 – 5 Dec 19	4 Jan 20	13 – 16 Jan 20	27 – 30 Jan 20	31 Jan 20
25 – 28 Nov 19	4 Oct 19	4 Oct 19	4 Nov 19	19 Nov 19	20 Nov 19	25 – 28 Nov 19	20 – 21 Jan 20	1 Feb 20	10 – 13 Feb 20	24 – 27 Feb 20	28 Feb 20

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