



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 September 2019
EMA/444946/2017
Product Development Scientific Support Department

Dates of 2020 SAWP meetings and submission deadlines

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

| SAWP Meeting dates 2020 | |
|--------------------------|--------------------------------|
| 1 st meeting | 13 January – 16 January 2020 |
| 2 nd meeting | 10 February – 13 February 2020 |
| 3 rd meeting | 9 March – 12 March 2020 |
| 4 th meeting | 14 April – 17 April 2020* |
| 5 th meeting | 11 May – 14 May 2020 |
| 6 th meeting | 8 June – 11 June 2020 |
| 7 th meeting | 6 July – 9 July 2020 |
| 8 th meeting | 31 August – 3 September 2020 |
| 9 th meeting | 28 September – 1 October 2020 |
| 10 th meeting | 26 – 29 October 2020 |
| 11 th meeting | 23 – 26 November 2020 |

Letter of intent latest template:

http://www.ema.europa.eu/docs/en_GB/document_library/Template_or_form/2009/11/WC5000119_10.pdf

*Tuesday start

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

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2020 Submission deadlines - Scientific advice, protocol assistance, qualification of biomarkers

| Presubmission phase | | | | | Evaluation phase | | | | | |
|---------------------|---|--------------------------------|---|----------------------------|--------------------|-------------------|----------------|----------------------------------|----------------|--|
| Start of procedure | Presubmission meeting** | | | Final 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 | | | | | | | |
| 13 – 16 Jan 2020 | 4 Nov 19 | 11 Nov 19 – 3 Jan 20 | 6 Dec 19 | 10 Jan 20 | 13 – 16 Jan 20 | 10 – 13 Feb 20 | 24 – 27 Feb 20 | 9 – 12 Mar 20 | 23 – 26 Mar 20 | 14 – 17 Apr 20 |
| 10 – 13 Feb 2020 | 6 Dec 19 | 16 Dec 19 – 31 Jan 20 | 17 Jan 20 | 7 Feb 20 | 10 – 13 Feb 20 | 9 – 12 Mar 20 | 23 – 26 Mar 20 | 14 – 17 Apr 20 | 27 – 30 Apr 20 | 11 – 14 May 20 |
| 9 – 12 Mar 2020 | 17 Jan 20 | 27 Jan 20 – 28 Feb 20 | 14 Feb 20 | 6 Mar 20 | 9 – 12 Mar 20 | 14 – 17 Apr 20 | 27 – 30 Apr 20 | 11 – 14 May 20 | 25 – 28 May 20 | 8 – 11 Jun 20 |
| 14 – 17 Apr 2020 | 14 Feb 20 | 24 Feb 20 - 3 Apr 20 | 20 Mar 20 | 8 Apr 20 | 14 – 17 Apr 20 | 11 – 14 May 20 | 25 – 28 May 20 | 8 – 11 Jun 20 | 22 – 25 Jun 20 | 6 – 9 Jul 20 |
| 11 – 14 May 2020 | 20 Mar 20 | 30 Mar 20 - 30 Apr 20 | 17 Apr 20 | 8 May 20 | 11 – 14 May 20 | 8 – 11 Jun 20 | 22 – 25 Jun 20 | 6 – 9 Jul 20 | 20 – 23 Jul 20 | 31 Aug – 3 Sep 20 |
| 8 – 11 Jun 2020 | 17 Apr 20 | 28 Apr 20 - 29 May 20 | 15 May 20 | 5 Jun 20 | 8 – 11 Jun 20 | 6 – 9 Jul 20 | 20 – 23 Jul 20 | 31 Aug – 3 Sep 20 | 14 – 17 Sep 20 | 28 Sep – 1 Oct 20 |
| 6 – 9 Jul 2020 | 15 May 20 | 25 May 20 - 26 Jun 20 | 12 Jun 20 | 3 Jul 20 | 6 – 9 Jul 20 | 31 Aug – 3 Sep 20 | 14 – 17 Sep 20 | 28 Sep – 1 Oct 20 | 12 – 15 Oct 20 | 26 – 29 Oct 20 |
| 31 Aug – 3 Sep 2020 | 12 Jun 20 | 22 Jun 20 - 21 Aug 20 | 17 Jul 20 | 28 Aug 20 | 31 Aug – 3 Sep 20 | 28 Sep – 1 Oct 20 | 12 – 15 Oct 20 | 26 – 29 Oct 20 | 9 – 12 Nov 20 | 23 – 26 Nov 20 |
| 28 Sep – 1 Oct 2020 | 17 Jul 20 | 17 Aug 20 - 18 Sep 20 | 4 Sep 20 | 25 Sep 20 | 28 Sep – 1 Oct 20 | 26 – 29 Oct 20 | 9 – 12 Nov 20 | 23 – 26 Nov 20 | 7 – 10 Dec 20 | 11 – 14 Jan 21 |
| 26 – 29 Oct 2020 | 4 Sep 20 | 14 Sep 20 - 16 Oct 20 | 2 Oct 20 | 23 Oct 20 | 26 – 29 Oct 20 | 23 – 26 Nov 20 | 7 – 10 Dec 20 | 11 – 14 Jan 21 | 25 - 28 Jan 21 | 8 – 11 Feb 21 |
| 23 – 26 Nov 2020 | 2 Oct 20 | 12 Oct 20 - 13 Nov 20 | 30 Oct 20 | 20 Nov 20 | 23 – 26 Nov 20 | 11 – 14 Jan 21 | 25 – 28 Jan 21 | 8 – 11 Feb 21 | 24 – 27 Feb 21 | 8 – 11 Mar 21 |

2020 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 | Final 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 (applicant, regulators and HTAs) | CHMP adoption | EUnetHTA / HTAB final recommendation letter |
| | Draft briefing document by | Draft briefing document by | | | | | | | | | |
| 13 – 16 Jan 20 | 4 Nov 19 | 4 Nov 19 | 6 Dec 19 | 16 Dec 19 | 10 Jan 20 | 13 – 16 Jan 20 | 20–21 Jan 20 | 24 Feb 20 | 9 – 12 Mar 20 | 23 – 26 Mar 20 | 27 Mar 20 |
| 10 – 13 Feb 20 | 6 Dec 19 | 6 Dec 19 | 17 Jan 20 | 27 Jan 20 | 7 Feb 20 | 10 – 13 Feb 20 | 17–18 Feb 20 | 23 Mar 20 | 14 – 17 Apr 20 | 27 – 30 Apr 20 | 04 May 20 |
| 9 – 12 Mar 20 | 17 Jan 20 | 17 Jan 20 | 14 Feb 20 | 24 Feb 20 | 6 Mar 20 | 9 – 12 Mar 20 | 16–17 Mar 20 | 20 Apr 20 | 11 – 14 May 20 | 25 – 28 May 20 | 29 May 20 |
| 14 – 17 Apr 20 | 14 Feb 20 | 14 Feb 20 | 20 Mar 20 | 30 Mar 20 | 8 Apr 20 | 14 – 17 Apr 20 | 21–22 Apr 20 | 19 May 20 | 8 – 11 Jun 20 | 22 – 25 Jun 20 | 26 Jun 20 |
| 11 – 14 May 20 | 20 Mar 20 | 20 Mar 20 | 17 Apr 20 | 27 Apr 20 | 8 May 20 | 11 – 14 May 20 | 18–19 May 20 | 22 Jun 20 | 6 – 9 Jul 20 | 20 – 23 Jul 20 | 24 Jul 20 |
| 8 – 11 Jun 20 | 17 Apr 20 | 17 Apr 20 | 15 May 20 | 25 May 20 | 5 Jun 20 | 8 – 11 Jun 20 | 15–16 Jun 20 | 20 Jul 20 | 31 Aug – 3 Sep 20 | 14 – 17 Sep 20 | 18 Sep 20 |
| 6 – 9 Jul 20 | 15 May 20 | 15 May 20 | 12 Jun 20 | 22 Jun 20 | 3 Jul 20 | 6 – 9 Jul 20 | 13–14 Jul 20 | 21 Sep 20 | 28 Sep – 1 Oct 20 | 12 – 15 Oct 20 | 16 Oct 20 |
| 31 Aug – 3 Sep 20 | 12 Jun 20 | 12 Jun 20 | 17 Jul 20 | 27 Jul 20 | 28 Aug 20 | 31 Aug – 3 Sep 20 | 7–8 Sep 20 | 12 Oct 20 | 26 – 29 Oct 20 | 9 – 12 Nov 20 | 13 Nov 20 |
| 28 Sep – 1 Oct 20 | 17 Jul 20 | 7 Aug 20 | 4 Sep 20 | 14 Sep 20 | 25 Sep 20 | 28 Sep – 1 Oct 20 | 5–6 Oct 20 | 09 Nov 20 | 23 – 26 Nov 20 | 7 – 10 Dec 20 | 11 Dec 20 |
| 26 – 29 Oct 20 | 4 Sep 20 | 4 Sep 20 | 2 Oct 20 | 12 Oct 20 | 23 Oct 20 | 26 – 29 Oct 20 | 2–3 Nov 20 | 07 Dec 20 | 11 – 14 Jan 21 | 25 - 28 Jan 21 | 29 Jan 21 |
| 23 – 26 Nov 20 | 2 Oct 20 | 2 Oct 20 | 30 Oct 20 | 9 Nov 20 | 20 Nov 20 | 23 – 26 Nov 20 | 30 Nov–1 Dec 20 | 22 Jan 21 | 8 – 11 Feb 21 | 24 – 27 Feb 21 | 26 Feb 21 |

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