



18 September 2019
EMA/444946/2017
Rev.3
Scientific Evidence Generation 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 updated |
| 9 th meeting | 28 September – 1 October 2020 |
| 10 th meeting | 26 – 29 October 2020 |
| 11 th meeting | 23 – 26 November 2020 |

Please note that from 19 October 2020 all types of applications will only be received electronically via IRIS EMA's secure online [IRIS platform](#).

Full details on how to apply are available in the [guidance for companies](#).

*Tuesday start

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Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

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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 2020 | 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 2020 | 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 (Written only format & F2F format)

| Start of procedure | Presubmission & validation phase | | | Evaluation phase | | | | | | | |
|--------------------|---|---|----------------------------|---------------------|-------------------|----------------|--|---|--|----------------|--|
| | Presubmission meeting | | Final briefing document by | Written-only format | | | | F2F format | | | |
| | Yes (exceptionally) | No (default) | | SAWP 1 | SAWP 2 | D40 | D55 | Written answers by applicant (to EUnetHTA, if F2F format) | SAWP 3 | D70 | D75 |
| | Letter of Intent and draft briefing document by | Letter of Intent and draft briefing document by | | Start of procedure | Reports discussed | CHMP Adoption | EUnetHTA / HTAB final recommendation letter (if Written-only format) | | Face to face meeting (applicant, regulators and HTAs, if F2F format) | CHMP adoption | EUnetHTA/ HTAB final recommendation letter (if F2F format) |
| 13 – 16 Jan 20 | 4 Nov 19 | 6 Dec 19 | 10 Jan 20 | 13 – 16 Jan 20 | 10 – 13 Feb 20 | 24 – 27 Feb 20 | 28 Feb 20 | n/a | 9 – 12 Mar 20 | 23 – 26 Mar 20 | 27 Mar 20 |
| 10 – 13 Feb 20 | 6 Dec 19 | 17 Jan 20 | 7 Feb 20 | 10 – 13 Feb 20 | 9 – 12 Mar 20 | 23 – 26 Mar 20 | 27 Mar 20 | n/a | 14 – 17 Apr 20 | 27 – 30 Apr 20 | 04 May 20 |
| 9 – 12 Mar 20 | 17 Jan 20 | 14 Feb 20 | 6 Mar 20 | 9 – 12 Mar 20 | 14 – 17 Apr 20 | 27 – 30 Apr 20 | 04 May 20 | n/a | 11 – 14 May 20 | 25 – 28 May 20 | 29 May 20 |
| 14 – 17 Apr 20 | 14 Feb 20 | 20 Mar 20 | 8 Apr 20 | 14 – 17 Apr 20 | 11 – 14 May 20 | 25 – 28 May 20 | 29 May 20 | n/a | 8 – 11 Jun 20 | 22 – 25 Jun 20 | 26 Jun 20 |
| 11 – 14 May 20 | 20 Mar 20 | 17 Apr 20 | 8 May 20 | 11 – 14 May 20 | 8 – 11 Jun 20 | 22 – 25 Jun 20 | 26 Jun 20 | n/a | 6 – 9 Jul 20 | 20 – 23 Jul 20 | 24 Jul 20 |
| 8 – 11 Jun 20 | 17 Apr 20 | 15 May 20 | 5 Jun 20 | 8 – 11 Jun 20 | 6 – 9 Jul 20 | 20 – 23 Jul 20 | 24 Jul 20 | n/a | 31 Aug–3 Sep 20 | 14 – 17 Sep 20 | 18 Sep 20 |
| 6 – 9 Jul 20 | 15 May 20 | 12 Jun 20 | 3 Jul 20 | 6 – 9 Jul 20 | 31 Aug–3 Sep 20 | 14 – 17 Sep 20 | 18 Sep 20 | n/a | 28 Sep – 1 Oct 20 | 12 – 15 Oct 20 | 16 Oct 20 |
| 31 Aug–3 Sep 20 | 12 Jun 20 | 17 Jul 20 ¹ | 28 Aug 20 | 31 Aug–3 Sep 20 | 28 Sep – 1 Oct 20 | 12 – 15 Oct 20 | 16 Oct 20 | 12 Oct 20 | 26 – 29 Oct 20 | 9 – 12 Nov 20 | 13 Nov 20 |
| 28 Sep – 1 Oct 20 | 17 Jul 20 | 4 Sep 20 | 25 Sep 20 | 28 Sep – 1 Oct 20 | 26 – 29 Oct 20 | 9 – 12 Nov 20 | 25 Nov 20 | 09 Nov 20 | 23 – 26 Nov 20 | 7 – 10 Dec 20 | 11 Dec 20 |
| 26 – 29 Oct 20 | 4 Sep 20 | 2 Oct 20 | 23 Oct 20 | 26 – 29 Oct 20 | 23 – 26 Nov 20 | 7 – 10 Dec 20 | 22 Dec 20 | 07 Dec 20 | 11 – 14 Jan 21 | 25 – 28 Jan 21 | 29 Jan 21 |
| 23 – 26 Nov 20 | 2 Oct 20 | 30 Oct 20 | 20 Nov 20 | 23 – 26 Nov 20 | 11 – 14 Jan 21 | 25 – 28 Jan 21 | 10 Feb 21 | 22 Jan 21 | 8 – 11 Feb 21 | 24 – 27 Feb 21 | 26 Feb 21 |

¹ All requests for Parallel Consultations with EUnetHTA must follow the procedure outlined in the Open Call for ED Requests and the Parallel Consultations Guidance document