



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 April 2020
EMA/CHMP/544996/2019 Rev 2

Timetable of procedure

Referral under Article 29(4) of Directive 2001/83/EC

Budesonide SUN and associated names

Procedure no: EMEA/H/A-29(4)/1492

Decentralised procedure no.:

NL/H/4194/001/DC

NL/H/4194/002/DC

NL/H/4194/003/DC

Procedural step:	Date:
Notification:	27 September 2019
Start of procedure (CHMP):	October 2019 CHMP
List of Questions:	17 October 2019
Submission of responses:	12 December 2019
Re-start of the procedure	02 January 2020
Rapporteur/co-rapporteur assessment report(s) circulated to CHMP:	10 January 2020
Comments:	17 January 2020
Updated Rapporteur/co-rapporteur assessment reports circulated to CHMP:	23 January 2020

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Procedural step:	Date:
CHMP list of outstanding issues:	30 January 2020
Submission of responses:	24 February 2020
Re-start of the procedure:	27 February 2020
Rapporteur/co-rapporteur assessment report(s) circulated to CHMP:	10 March 2020
Comments:	16 March 2020
Updated Rapporteur/co-rapporteur assessment report(s) circulated to CHMP:	20 March 2020
CHMP opinion:	March 2020 CHMP
Re-examination - Receipt of letter of intent from Applicant:	2 April 2020
Re-examination - Receipt of detailed grounds from MAH:	28 April 2020
Re-examination - Start of re-examination procedure:	29 April 2020
Re-examination - Rapporteur/co-rapporteur assessment report(s) circulated to CHMP:	28 May 2020
Re-examination – Comments:	03 June 2020
Re-examination - Rapporteur/co-rapporteur updated assessment report(s) circulated to CHMP:	09 June 2020
Re-examination - CHMP Opinion:	June 2020 CHMP