



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

28 February 2019  
EMA/CHMP/349538/2018 Rev. 2

## Timetable for the procedure

Referral under article 31 of Directive 2001/83/EC

Bacterial lysates-containing medicinal products for respiratory conditions

Procedure no: EMEA/H/A-31/1465

Procedural step:	Date
Notification:	8 June 2018
Start of the procedure (CHMP):	June, 2018 CHMP
List of questions:	28 June 2018
Submission of responses:	27 August 2018
Re-start of the procedure:	20 September 2018
Rapporteur/co-rapporteur assessment report(s) circulated to CHMP:	3 October 2018
Comments:	8 October 2018
Updated Rapporteur/co-rapporteur assessment reports circulated to CHMP:	11 October 2018
CHMP list of outstanding issues:	October, 2018 CHMP
Submission of responses:	10 January 2019
Re-start of the procedure:	31 January 2019



<b>Procedural step:</b>	<b>Date</b>
Rapporteur/co-rapporteur joint assessment report(s) circulated to CHMP:	08 February 2019
Scientific Advisory Group meeting:	12 February 2019
Comments:	15 February 2019
Updated Rapporteur/co-rapporteur joint assessment reports circulated to CHMP:	21 February 2019
CHMP list of outstanding issues:	28 February 2019
Submission of responses:	2 May 2019
Re-start of the procedure:	30 May 2019
Rapporteur/co-rapporteur joint assessment report(s) circulated to CHMP:	5 June 2019
Comments:	12 June 2019
Updated Rapporteur/co-rapporteur joint assessment reports circulated to CHMP:	18 June 2019
CHMP list of outstanding issues or CHMP opinion:	June, 2019 CHMP