



24 November 2021  
EMA/HMPC/483588/2020  
Committee on Herbal Medicinal Products (HMPC)

## Public statement on *Saccharomyces cerevisiae* CBS 5926

### Final

Discussion in Working Party on European Union Monographs and European Union List (MLWP) and Committee on Herbal Medicinal Products (HMPC)	September 2015 November 2015 February 2016 April 2016 May/June 2016 July 2019 January 2020 March 2020 July 2020 September 2020 November 2020 January 2021 March 2021 May 2021
Adopted by HMPC for release for consultation	05 May 2021
End of consultation (deadline for comments) <sup>1</sup> .	31 August 2021
Re-discussion in HMPC	September 2021 November 2021
Adopted by HMPC	24 November 2021

<b>Keywords</b>	Herbal medicinal products; HMPC; Public statements; <i>Saccharomyces cerevisiae</i> CBS 5926; yeast
-----------------	---

<sup>1</sup> No comments were received during the period of public consultation. Therefore, the final public statement is published together with the final assessment report and list of references, without an 'Overview of comments received during the public consultation'.



# Public statement on *Saccharomyces cerevisiae* CBS 5926

## PROBLEM STATEMENT

The HMPC decided to prepare a European Union herbal monograph on *Saccharomyces cerevisiae* CBS 5926 as announced in the July 2013 HMPC meeting report. A call for submission of scientific data was published on the EMA website with a submission date 15 May 2014.

A comprehensive literature search was conducted and available data, including information on products on the market in the European Union, were assessed in relation to the requirements laid down in Directive 2001/83/EC and its Annex I, in particular Article 1, Article 10a and Chapter 2a.

After extensive discussions in the Committee, taking into account that fungi are in general included in the 'herbal substance' definition of the Directive 2001/83/EC and on the other hand living yeasts are covered by the Live Biotherapeutic Products general monograph of the European Pharmacopoeia, no absolute majority required for adoption of the monograph was achieved.

The HMPC concluded therefore that the following requirement for the establishment of a European Union herbal monograph on traditional and well-established herbal medicinal products containing *Saccharomyces cerevisiae* CBS 5926 is not fulfilled:

- the requirement laid down in Article 1 of Directive 2001/83/EC on the definition of herbal substance (despite the existence of data on the safety, efficacy and historical data on the medicinal uses within the European Union of products containing *Saccharomyces cerevisiae* CBS 5926).

## CONCLUSIONS

Based on the nature of the active substance, the HMPC is of the opinion that a European Union herbal monograph on *Saccharomyces cerevisiae* CBS 5926 cannot be established.

To read more about the assessment carried out, a link is provided to the page where to access the final assessment report on *Saccharomyces cerevisiae* CBS 5926 and its list of references.

<https://www.ema.europa.eu/en/medicines/herbal/saccharomyces-cerevisiae-cbs-5926>