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Committee on Herbal Medicinal Products (HMPC)

Public statement on *Saccharomyces cerevisiae* CBS 5926

Draft

Discussion in Working Party on European Union Monographs and European Union List (MLWP) and Committee on Herbal Medicinal Products (HMPC)	Sep 2015
	Nov 2015
	Feb 2016
	Apr 2016
	May/Jun 2016
	Jul 2019
	Jan 2020
	Mar 2020
	Jul 2020
	Sep 2020
	Nov 2020
	Jan 2021
	Mar 2021
May 2021	
Adoption by HMPC for release for consultation	05 May 2021
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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 the 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 draft assessment report on *Saccharomyces cerevisiae* CBS 5926 and its list of references.

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

The HMPC will welcome the provision of the necessary data to allow continuation of the assessment work.