



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

12 October 2023  
EMA/461358/2023  
Press Office

## Start of union reviews

CHMP meeting of 9-12 October 2023

**Table 1. Start of reviews for centrally authorised medicines**

Name	INN	Type of procedure	Scope
Ocaliva	Obeticholic acid	Article 20 of Regulation (EC) 726/2004	The procedure is triggered by the European Commission asking for a review of Ocaliva.  This was prompted by the final study results raising concerns over potential lack of efficacy and worsening safety profile for Ocaliva in its approved indication.

**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands  
**Address for visits and deliveries** Refer to [www.ema.europa.eu/how-to-find-us](http://www.ema.europa.eu/how-to-find-us)  
**Send us a question** Go to [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact) **Telephone** +31 (0)88 781 6000

An agency of the European Union

