



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY
Directorate D – Medical products and Innovation
D1 – Medicines – policy, authorisation and monitoring
Head of unit

Brussels, 22 May 2024

**NOTE TO THE MEMBERS OF THE STANDING COMMITTEE ON MEDICINAL PRODUCTS FOR
HUMAN USE/STANDING COMMITTEE ON VETERINARY MEDICINAL PRODUCTS**

**Subject: Adoption of COMMISSION IMPLEMENTING DECISION
granting marketing authorisation under Regulation (EC) No
726/2004 of the European Parliament and of the Council for
"Omlyclo - Omalizumab", a medicinal product for human use**

EU/1/24/1817 - EMEA/H/C/005958/0000

IMPORTANT:

- Please note that the original, signed, paper version of the Commission decision and associated annexes will not be sent to marketing authorisation holders by courier. **It will be sent electronically only, via a separate e-mail that will contain a request to acknowledge receipt of the documents.**
- Please ensure that someone is available to access the contact e-mail address you have supplied to the European Medicines Agency and to reply confirming receipt of the documents. Please check the designated e-mail account regularly if you are expecting to receive a Commission decision.

The Commission adopted the above-mentioned Decision on 16 May 2024.

The Decision will be notified forthwith to the addressee(s) of the Decision.¹

The Decision will be published for information in all official languages of the EU in the Union Register of Medicinal Products (http://ec.europa.eu/health/documents/community-register/index_en.htm) after the Decision has been notified. Attention should be drawn to the fact that, under the general rules of the EC Treaty, a Decision is a legal act whose publication is not obligatory to be binding.

Olga Solomon
pp. Jones Sharon

Cc: Marketing authorisation holder (Contact person, only in centralised procedure);
EMA (Product team leader, secretary)

¹ In case of centralised procedure: Marketing Authorisation Holder; In case of referral or PSUR (Periodic Safety Update Reports) procedures: Member States (via the Permanent Representations to the European Union)