



**European Alliance for
Vision Research and
Ophthalmology**



Briefing

**CHMP early contact with patient and healthcare professional organisations
&
Third party interventions**

in the evaluation of new marketing authorisation applications

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Transparency Register ID number: [221589017973-83](https://ec.europa.eu/transparency/register/id/221589017973-83)

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This briefing is to inform on the processes for early contact with patient and healthcare professional organisations, and third party interventions during the evaluation of new marketing authorisation applications (MAA).

Early contact with patient and healthcare professional organisations

The process for early contact with patient and healthcare professional organisations is followed by the Committee for Human Medicinal Products (CHMP) of the European Medicines Agency during the evaluation of new MAA since May 2023. Healthcare professional organisations were not consulted for applications submitted before then.

A core group at CHMP selects the products for consultation. Not all applications are subject to the consultation.

The early consultation aims to collect high level input on the standard of care, treatment duration, therapeutic/unmet medical needs, benefits healthcare professionals would hope for in new medicines, and level of side-effects they would consider manageable for patients. The early consultation does not aim to collect positions on the medicinal product under assessment from the consulted organisations.

Organisations receive only the name of the active ingredient and proposed indication; no information submitted by the applicant is shared with them.

The input from the organisations is shared with the applicant of the concerned procedure.

For the background to this process and for additional details: [process and FAQ](#)

Third party interventions

Third parties can submit written observations, which should be taken into account during the scientific assessment if considered relevant by the concerned EMA Scientific Committee.

The third party intervention is shared with the applicant of the concerned procedure(s).

For more information on how the EMA handles third party interventions:

[2.1. Third party interventions for WP - Fabrizio Boccacci \(EMA\) \(europa.eu\)](#).