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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): mycophenolate mofetil, mycophenolic acid

Procedure No. EMEA/H/C/PSUSA/00010550/202105

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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
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSURs for mycophenolate mofetil, mycophenolic acid, the scientific conclusions of CHMP are as follows:

In view of available data on severe course of COVID-19 infection from the literature and in view of a plausible mechanism of action, the PRAC considers a causal relationship between mycophenolate mofetil, mycophenolic acid and severe course of COVID-19 infection is at least a reasonable possibility. The PRAC concluded that the product information of the centrally authorised medicinal products and nationally authorised medicinal products containing mycophenolate mofetil, mycophenolic acid should be amended accordingly.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the marketing authorisations

On the basis of the scientific conclusions for mycophenolate mofetil, mycophenolic acid the CHMP is of the opinion that the benefit-risk balance of the medicinal products containing mycophenolate mofetil, mycophenolic acid is unchanged subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisations should be varied.