

How the European Medicines Agency dealt with the authorisation of the medicine Kalydeco for use by children with a specific form of cystic fibrosis

Case 222/2020/EWM - Opened on 21/02/2020 - Decision on 03/06/2020 - Institution concerned European Medicines Agency (No maladministration found) |

The complaint concerned the time taken by the European Medicines Agency (EMA) to authorise Kalydeco, a medicine for treating cystic fibrosis, for use in children with a specific form of the disease that affects the complainant's child.

The Ombudsman found that no unjustified delays had occurred. During the inquiry, EMA informed the complainant and the Ombudsman that, after reviewing all the relevant evidence, its scientific experts had approved Kalydeco for use in children with the form of cystic fibrosis in question. The Ombudsman closed the inquiry with a finding of no maladministration.