Ombudsman inquiry strengthens transparency and objectivity of EMA's assessment of new medicines

Case OI/7/2017/KR - Opened on 17/07/2017 - Decision on 17/07/2019 - Institution concerned European Medicines Agency (No further inquiries justified)

26 November 2019 - An Ombudsman inquiry into how the European Medicines Agency (EMA) engages with pharma companies before they apply for market access for their medicines has led to several measures to improve the transparency and objectivity of the process.

Working constructively with the Ombudsman, EMA has agreed to introduce a log of the scientific advice concerning medicines in the market approval process. This advice will be made public once the medicine is allowed to be sold in Europe. EMA has also said that, to the greatest extent possible, the experts that are prominently involved in advising pharmaceutical companies in the pre-market application phase will not be those that draft EMA's evaluation report for a new medicine.