Response to Consultation on EMA Engagament with Manufacturers for Marketing Medicines

Consultation Response | 31 January, 2019 | Download PDF

In 2017, the European Ombudsman opened an inquiry directed at the European Medicines Agency (EMA). This looked at the 'pre-submission activities' between individual medicine developers and the EMA which occurs prior to these developers seeking authorisation when marketing medicines.

After discussing this issue with the EMA, the Ombudsman sought input from relevant parties on this issue. This encouraged interested parties to respond to a series of questions that examined the relationship between the EMA and individual medicine developers around marketing medicines and other issues. These questions ranged from seeking input on the EMA's use of experts, to asking whether there is a need to enhance transparency of scientific advice EMA provides to medicine developers. In total there are eight questions for which Health Action International provided feedback.

Ultimately, Health Action International advocated for a clear separation of roles between advisors and marketing authorisation assessors and greater transparency regarding the products accepted into the scheme. This is because at present, the EMA does not explain under which grounds it has been considered that a selected product meets the criteria based on the data submitted to support the request for eligibility.

Health Action International formulated a response to this consultation by the European Ombudsman. Download the PDF document to read our full answers to the questions posed by the Ombudsman.

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