Comments of the complainant (complaint: 1851/2022/kr) regarding the report on the inspection of documents and on the meeting of the European Ombudsman inquiry team with representatives of the European Medicines Agency on 10 july 2023

The spirit of the applicable legislation and EMA guidance (collectively 'EMA regulation') pertaining to installment and the role of an ad-hoc expert group (AHEG) in re-examination procedures, at least suggests that the advice given by an AHEG weighs in considerably in the decision-making process of the Committee for Human Medicinal Products (CHMP). An AHEG should be made up of independent field experts capable of addressing the grounds for re-examination. We respectfully argue the following:

(i) In contrast to what is suggested in this report, EMA regulation consider a consultancy position with the pharmaceutical industry a major conflict of interest for an expert, independent of the scope of the consultancy services provided by the expert to the industry.

The company that hired the expert as a consultant is one of the leading and widely known pharmaceutical companies worldwide and is also engaged in developing and marketing medical devices, it can therefore not be labelled as a medical device company.

The claim that the expert was only consulting about medical devices was not verified by an inspection of the contract between the company and the consultant. In addition, many medical devices are being developed to support in support of medicinal treatment modalities of AMD and could be considered competitive to [redacted]. Therefore, involvement in the development of a medical device should be considered a conflict of interest that the expert should have declared to the EMA.

The argument of the EMA about the scope of the consultancy being medical devices rather than pharmaceuticals contradicts their position that the use of experts with a conflict-of-interest is unavoidable if experts having specific expertise are needed. How can specific expertise be irrelevant to identify a conflict-of-interest, while being of high relevance to have available in the ad-hoc expert group (AHEG)?

This report confirms that the opinions of the AHEG were formulated in a meeting in which both the restricted experts (with a conflict of interest) and the unrestricted experts participated, although, according to the regulations, the role of the restricted experts should be only to answer specific scientific questions. Non-restricted experts only contribute to the discussion in the expert group and have the possibility to react to the outcome of the expert meeting as documented in (draft) minutes.

The argument of the EMA for not taking more time to find experts without conflict of interests is not convincing. Clock stops in the EMA/CHMP procedures are quite common and, in this case where the integrity of the reassessment procedure was at stake, would have been completely acceptable also for the applicant (i.e., [redacted].).

(ii) The invited experts, although being respected ophthalmologists, were not necessarily experts on the remaining clinical methodological issues at hand. After all, the grounds for re-examination were of a clinical methodological nature.

(iii) The questions asked to the AHEG expert group did not specifically address the main issue around a potential residual safety risk with [redacted] (rated as negligible by the applicant),

and whether the hypothesis that Avastin and [redacted] have a similar safety profile could be tested in a methodologically sound clinical study (pre-approval).