EMA's opaque advice to drug companies

Some drugs at an advanced (or not so advanced) stage of clinical development are not swiftly authorised. On the grounds of avoiding such "failures", the European Medicines Agency (EMA) offers "scientific advice" to drug companies to help them compile their marketing authorisation application (1). A public drug regulatory agency would be expected to set standards for clinical trials, such as which endpoint, method and comparator to use, through transparent, public, detailed written guidelines, not through confidential tailored advice.

In 2015, *Prescrire* and the Medicines in Europe Forum highlighted the risk that this secret, personalised scientific advice, for which the EMA sometimes charges a fee, could undermine the Agency's impartiality and credibility (1). In 2017, the European Ombudsman highlighted the lack of transparency surrounding scientific advice, and publicly asked the director of the EMA to answer a list of questions about the existence of procedures to manage the risk of bias (2). In 2016, the EMA received 582 requests for scientific advice. More than half of the 81 European marketing authorisations (including 27 new active substances) were granted after the pharmaceutical company received scientific advice from the EMA regarding clinical trials, preclinical studies or pharmaceutical quality issues (3).

EMA advice is commonly sought for conditional marketing authorisations, i.e. those granted early along with a request for additional post-marketing evaluation. For example, the EMA issued advice on 18 of the 30 conditional marketing authorisations it granted between 2006 and 2016. And 71% of conditional marketing authorisation applications that adhered to the EMA's scientific advice were approved, versus 40% of those that did not adhere to it (4).

The EMA's conflicting roles. These figures are open to various interpretations. Given the lack of transparency in the procedures in place to safeguard the EMA's objectivity in these situations, one interpretation is that it is compromised by the close working relationships created between EMA and drug company employees.

The European Ombudsman is concerned by this risk and has rightly called for transparency regarding these activities (2). The EMA's credibility in its role of patient protection is at stake. Lack of transparency fuels the suspicion that it may actually be protecting pharmaceutical companies instead of public health.

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Sources **1-** Prescrire Rédaction "Conseils scientifiques de l'EMA aux firmes: menace pour l'indépendance" *Rev Prescrire* 2015; **35** (384): 780-781. **2-** "Letter from the European Ombudsman to the European Medicines Agency opening strategic inquiry OI/7/2017/KR into pre-submission activities organised by the Agency" 17 July 2017. www.ombudsman.europa.eu accessed 8 September 2017: 3 pages. **3-** EMA "Annual report 2016": 88 pages. **4-** EMA "Conditional marketing authorisation - Report on ten years of experience at the European Medicines Agency" 2017: 42 pages.

EDITORIAL