Reporting irregularities that may affect medicines

10/04/2017

EMA Board adopts new policy on handling information on alleged improprieties from external sources

The European Medicines Agency's (EMA) Management Board has adopted a new policy on how EMA handles allegations of improprieties received from external parties. These improprieties may include allegations of departures from standards of good practices that could have an impact on the evaluation and supervision of medicines.

The goal is to create an environment where individuals from outside the Agency feel confident to raise their concerns on improprieties in their area of work. The policy helps EMA assess these reports and co-ordinate any further investigation in a structured way, while protecting the confidentiality of the reporter.

Since 2013, EMA has received a total of 43 reports that relate, for example, to the manufacturing of medicines or the conduct of clinical trials. Although no formal policy has existed until now, all reports were dealt with in line with the principles included in the new policy.

A dedicated email inbox, reporting@ema.europa.eu, has been created. Individuals external to EMA can raise their concerns by sending a message or providing information to this address. They can also send a letter to the Agency. Their identity will be kept confidential.

If the allegations concern a centrally authorised medicine, EMA will coordinate the investigation. If there are any concerns that the improprieties may affect the balance of benefits and risks of the medicine, EMA's scientific committees may consider regulatory action.

If the allegations concern a nationally authorised medicine, EMA may, on a case-by-case basis, refer the matter to the national medicines agency in the EU Member State where the concerned medicine is authorised.

If there is a suspicion that fraud is involved, EMA will transmit the report to the European Anti-Fraud Office (OLAF) in accordance with the existing arrangements between the two institutions.

The policy was adopted by the Management Board at its March meeting and came into effect on 17 March 2017. It was prepared in consultation with the European Commission and OLAF.