

## **APPEALS PROCEDURE IN RESPECT OF PHARMACEUTICAL ACTIVITIES**

Any stakeholder or customer of the Medicines Authority who feels aggrieved by any decision taken in respect of pharmaceutical activities can present a written submission to the Inspection Review Group (IRG) of the same Authority within 14 days of receipt of such decision. The appeal or request for review shall clearly and comprehensively state the grounds and reasons, provide all evidence and documentation to sustain the claims and shall be accompanied by the appropriate fee. The IRG has the remit to consider and decide on any complaint in respect of pharmaceutical activities, such as when a decision had been taken by the Inspectorate not to approve a licence, to suspend or revoke a licence, to remove (or not approve) a Qualified or Responsible Person from (on) a licence or to recall a product.

The appeals procedure will be managed according to the quality system and internal procedures of the Medicines Authority. Strict confidentiality will be maintained and the complainant will be given the opportunity to make his case and make a representation to the IRG.

The IRG undertakes to review the cases presented within the shortest possible timeframe. The final decision shall be communicated to the appellant in writing. A second appeal can be lodged within 14 days of receipt of the first decision. In such cases the IRG shall be convened immediately to reconsider the case. The second decision of the IRG will be considered as final.