Medicines & Healthcare products
Regulatory Agency

Actions as a result of referral to the Inspection Action Group (“IAG”)

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Possible action as a result of IAG referral

IAG1 considers issues related to good manufacturing practice (“GMP”), good distribution practice (“GDP”) and blood establishment authorisations (“BEAs”).

Possible actions as a result of a referral are:

- refusal to grant or vary a licence
- proposal to suspend licence for a stated period
- notification of immediate suspension of a licence
- proposal to revoke or vary the licence
- removal of named individuals from a licence
- requests for information issued to named individuals on a licence
- referral of a named individual on a licence to their professional body
- a meeting with the agency
- statement of GMP non-compliance
- conditioned GMP Certificate
- compliance monitor oversight
- increased inspection frequency/follow-up/triggered inspections
- cease and desist order (BEA)
- referral to MHRA Criminal Enforcement Unit
- referral to the MHRA Defective Medicines Reporting Centre (“DMRC”)
- referral to other Regulators

IAG2 considers issues related to good clinical practice (“GCP”) and good pharmacovigilance practice (“GPvP”).

Possible actions as a result of a referral are:

- Infringement Notice (notification of the EMA and European Commission of any infringement notices relating to a Category 2 UK authorised product)
- suspension/revocation of a clinical trial authorisation/phase 1 accreditation
- increased inspection frequency/follow-up/triggered inspections (e.g. GCP issues leading to GMP inspections)
- referral for marketing authorisation actions (suspension, variation, revocation)
- liaison and coordinated action with regulatory partners in line with information sharing agreements
- request for information issued to the Qualified Person responsible for pharmacovigilance (QPPV)
- a meeting with the agency
- referral to MHRA Criminal Enforcement Unit
- referral to the MHRA Defective Medicines Reporting Centre (“DMRC”)
- referral to other Regulators

In the case of inspections in third countries:

- issuing a statement of non-compliance with GMP (which could lead to refusal to name a site on marketing authorisation or recommendation to remove a site from marketing authorisation)
- removal of the site from the marketing authorisation following adverse inspections of active pharmaceutical ingredients (API) site

- suspension of a clinical trial following adverse inspections of investigational medicinal products (IMP)

Compliance Monitor pilot

Since April 2022, the MHRA has been piloting a programme for GMP and GDP remediation supervision by eligible consultants acting as Compliance Monitors ("CM"). The CM will work with the licence/authorisation holder to deliver actions identified in a Compliance Protocol ("CP"), that has been agreed with the MHRA. High-level updates on progress against the CP will be communicated to the MHRA at a pre-agreed frequency (provision of additional detail will be by exception against the CP requirements).

Upon completion of the CP, the CM will communicate to the MHRA that the licence/authorisation holder's site is ready for inspection. The MHRA will then inspect to determine if the site can be removed from IAG oversight. The MHRA will maintain the right to carry out inspection(s) prior to the completion of the CP if considered necessary.

See the following blogs for more detail:

- Compliance Monitor process (Part 1) – An introduction
- Compliance Monitor Process (Part 2)– CM role and application process

What to do if you are referred

Treat a referral as a requirement to immediately correct inspection deficiencies and report actions to the IAG via responses to MHRA letters.

- **Immediate Suspension**: No right to appeal but can challenge in the High Court. Focus on addressing deficiencies during this time.
- **Proposed Suspension/Variation/Revocation**:
    - make written or oral representations in respect of the proposed action.
    - Requests to make oral representations must be accompanied by the fee (£11,000). The hearing provides an opinion, the final decision rests with the Licensing Authority.
    - Any representations will be considered before a decision is made.

Inspector activities outside of formal inspection

The ongoing review of information by the inspectors for companies under IAG oversight can elicit additional fees for inspector time. This issue is set out in the linked blog.

The legal basis for action

Links to the legislation:

Human Medicines Regulations 2012

The Medicines for Human Use (Clinical Trials) Regulations 2004

The Blood Safety and Quality Regulations 2005

Contact

For further information please email:

IAGSecretariat@mhra.gov.uk

IAG2Secretariat@mhra.gov.uk

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