



## Post inspection continuation of regulatory action

In situations where prior inspection of a manufacturer / distributor has identified critical and/or major deficiencies resulting in consideration of regulatory action by the Licensing Authority, a re-inspection may be performed to review the actions arising.

Further deficiencies identified during the re-inspection will be independently reviewed by a senior or expert inspector, and the final classification will be confirmed in writing. The timescale for responding to the deficiencies will be confirmed in the post inspection letter (typically 7 days).

Where the company's remediation plan remains in progress, the original deficiencies resulting in referral to the Licensing Authority continue to be valid for the purposes of considering regulatory action until it is confirmed that effective remedial actions have been implemented (usually upon re-inspection). The manufacturer / distributor will have previously been notified of possible regulatory actions and their implications; these can be clarified by the inspector or the Licensing Authority on request.

The re-inspection findings will be provided to the Licensing Authority for their review. Further correspondence on the outcome of the inspection in terms of continuing regulatory action will be communicated separately by the Licensing Authority. It is normal practice for this to take place following receipt and assessment of the company's post inspection responses unless the Licensing Authority considers that immediate action is required in the interests of safety.

Any action taken will consider the potential impact to supply chain for products considered medically critical (products for which there is no available therapeutic alternative, as agreed by the national competent authority). Any restricted regulatory actions taken in the interests of maintaining the supply of medically critical products will be notified by the Licensing Authority as subsequent correspondence.

Regulatory restrictions are not a permanent barrier to manufacturing or distribution activity, and will be lifted if the manufacturer / licence holder is able to demonstrate (usually upon re-inspection) the effective implementation of corrective actions which address the identified GMP / GDP deficiencies. The regulatory action process is administered on behalf of the Licensing Authority by the Inspection Action Group (IAG). This multidisciplinary group meets regularly, usually fortnightly, to deal with ongoing business and to consider new referrals. Ad hoc meetings may be called by the Chairman for urgent cases. The company may wish to provide an interim response to the IAG for discussion at their next meeting, prior to submitting their formal response to the written inspection deficiency notice. The date of the next meeting can be obtained from the site inspector.

It is very important for the company to maintain open communication channels with the IAG throughout the process, and notify any significant changes in GMP compliance (positive or negative), including delays in implementing corrective action commitments, in a timely manner.