



Post inspection consideration of regulatory action – UK Wholesaler

The inspection conducted at the above named facility has following independent review by a senior inspector identified critical GDP deficiencies and / or breaches of The Human Medicines Regulations 2012. You will have 14 days from the date of receipt of the post inspection letter to respond with your proposals for corrective action, unless it is considered necessary to suspend a licence with immediate effect in the interests of safety.

There may be grounds for the Licensing Authority to take formal action under the Human Medicines Regulations 2012:

- regulation 23 for refusal to grant a wholesale dealers licence application, or
- regulation 26 to take formal action against an existing wholesale dealers licence or.
- regulation 29 to refuse to vary a wholesale dealers licence

It is normal practice for a licence holder or applicant to be given the opportunity to respond to the reported GDP deficiencies prior to taking regulatory action against the licence. The implications of regulatory action are as follows:

- **Action against your wholesale dealers authorisation** (either suspension in full or variation to remove specified activities, facilities or sites) will be preceded by a notice period of at least 28 days, unless the Licensing Authority considers that immediate action is required to protect public health. It is a criminal offence under regulation 34(1) of the Human Medicines Regulations to distribute medicinal products without the required licence.
- **Action to remove named persons from a wholesale dealers authorisation** (The Responsible Person) will be preceded by a notice period of at least 28 days. Unless there are other persons already named on the wholesale dealers licence as responsible, the licence holder will also have to submit a variation to propose a replacement to maintain a valid licence. Not having a named Responsible Person is grounds for suspension, so a 28 day notice to remove an RP following critical findings will also trigger a 28 notice of proposed suspension.
- **The issuance of a Statement of Serious Non-compliance with GDP** will prevent the procurement, sale and supply of medicinal products from the date of publication, unless otherwise indicated. Any previous GDP certificates will be withdrawn. The Statement of Serious Non-compliance with GDP will also be publicly visible on the EudraGMDP website (<http://eudragmdp.ema.europa.eu/>). Medicinal products in existing stock between the date of publication of the document and any subsequent return to GDP compliance (confirmed following re-inspection) will be considered suitable for future sale or supply following a return to compliance, unless otherwise notified by the Licensing Authority.

There are opportunities for the licence holder to submit representations in response to a notice of proposed regulatory action, which will be outlined in correspondence from the Licensing Authority if such action is proposed. This is in addition to the post inspection responses to address the identified deficiencies.

The above actions are not a permanent barrier to distribution activity, and regulatory restrictions will be lifted if the licence holder is able to demonstrate (usually upon re-inspection) the effective implementation of corrective actions which address the identified GDP deficiencies and / or failures to comply with the obligations of the Human Medicines Regulations.

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 Chair of IAG for urgent cases involving patient safety. You may wish to provide an interim response to the IAG for discussion at their next meeting, prior to submitting your formal response to the written inspection deficiency notice. The date of the next meeting can be obtained from your 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 compliance (positive or negative), including delays in implementing corrective action commitments, in a timely manner. Contact details will be provided in the initial correspondence from IAG to the company.

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