Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Post inspection consideration of regulatory action – 'Specials' manufacturers

Potentially critical GMP / GDP deficiencies are independently reviewed by a senior or expert inspector prior to the final classification being confirmed in writing. The manufacturer will have 7 days from the date of receipt to respond with their proposals for corrective action.

Critical and / or multiple major deficiencies may provide grounds for the Licensing Authority to take action under regulation 23 of the Human Medicines Regulations 2012 (as amended) for refusal to grant a Manufacturers (Specials) licence application, or under regulation 26 to take formal action against an existing Manufacturers (Specials) licence.

It is normal practice for a manufacturer to be given the opportunity to respond to the reported GMP deficiencies prior to taking regulatory action, unless it is considered necessary to suspend licences with immediate effect in the interests of safety. The implications of regulatory action are as follows:

- **Action against manufacturing licences** (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 manufacture or distribute medicinal products without the required licence.

- **Action to remove named persons from a manufacturing authorisation** (e.g. Persons named as responsible for Quality Control). Unless there are other persons already named on the manufacturing authorisation as responsible for the relevant role, the licence holder will also have to submit a variation to propose a replacement in order to maintain a valid authorisation.

There are opportunities for the manufacturer 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 manufacturing or distribution activity, and regulatory restrictions will be lifted if the manufacturer is able to demonstrate (usually upon re-inspection) the effective implementation of corrective actions which address the identified GMP deficiencies.

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.

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 manufacturer 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. Contact details will be provided in the initial correspondence from IAG to the company.

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