



## Post inspection consideration of Compliance Management action – ‘Specials’ manufacturers

Inspections where major and/or potentially critical GMP / GDP deficiencies are identified may be escalated to senior Inspectorate staff for consideration under the Compliance Management process. The objective of this non-statutory process is to escalate the inspection case management and direct companies towards a state of compliance, thus protecting public health and avoiding the need for regulatory action.

The inspection case management actions required may include meetings and correspondence with company senior management to alert them to the compliance concerns, clearly outlining the consequences of continued non-compliance, and close monitoring of compliance improvement work through inspections and written updates from the company.

The initial and on-going Compliance Management review will also determine the need for referral to the Licensing Authority to consider whether there are grounds 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. This may be based upon the current inspection findings, inadequacy of proposals to correct the inspection findings, or failure to implement commitments in an effective or timely manner. The implications of formal regulatory actions are as follows:

- **Action against manufacturing licences** (either suspension in full or variation to remove specified activities, facilities or sites) which in most cases is 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 to maintain a valid authorisation.

Following independent review by a senior or expert inspector, the final classification of the deficiencies will be confirmed in writing within 14 days. The licence holder will have a further 21 days from the date of receipt to respond with their proposals for corrective action. Any further compliance monitoring actions will be communicated as separate correspondence.

It is very important for the licence holder to maintain open communication channels with the site inspector and Compliance Management Team (CMT) 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 CMT to the company.