## Problem statement


- Article 46f requires the holder of the manufacturing authorisation to ensure that excipients are suitable for use in medicinal products by ascertaining appropriate good manufacturing practice on the basis of a formalised risk assessment.
- In Article 47 it is stated that the Commission shall adopt guidelines on the formalised risk assessment for ascertaining the appropriate good manufacturing practice for excipients.

EFPIA supports the requirements of the new legislation, but our concern is that its implementation may lead to a proliferation of regulatory guidance. Current regulations, practices and standards, which have been established, for example by the excipient suppliers, medicinal product manufacturers and Pharmacopoeias and which ensure excipient quality, need to be taken into account.

## EFPIA position

Pharmaceutical manufacturers are responsible for ensuring that excipients used in medicinal products are fit for purpose. This principle is already embedded in EU GMP for medicinal products for human use (e.g. EU GMP Chapter 5). In accordance with the current requirements of EU GMP, the pharmaceutical industry has vendor management systems in place. In these programmes, the quality systems at the excipient supplier and the corresponding Good Distribution Practices associated with the excipient in the supply chain are monitored and audited. Risk assessments are routinely performed taking into account the type of excipient, the quality history of the excipient supplier and the reliability and integrity of the supply chain. The use of the excipient in the finished product and its route of administration is also considered in the risk assessment.

EFPIA Recommends the following:

- The requirements of the FMD legislation to perform and document a formalised risk assessment and consider the source and intended use of excipients as well as previous instances of quality defects (Article 46f) should be integrated into existing vendor management programmes.

---

1 Defined in FMD as 'Any constituent of a medicinal product other than the active substance and the packaging material.'
The guidelines to be adopted by the Commission (Article 47) on the formalised risk assessment for ascertaining the appropriate good manufacturing practice for excipients should fully reflect the risk management principles already described in Part III EU GMP: Quality Risk Management (ICH Q9).

In ascertaining the appropriate good manufacturing practice for excipients, existing quality standards and ongoing initiatives to ensure excipient quality through manufacturing, sourcing and securing the supply chain should be referenced e.g. ANSI standard for pharmaceutical excipients, IPEC/PQG Excipient Guide 2006 (based on ISO framework), GMP and USP General Chapter <1078>, WHO requirements for “Good trade and distribution practices for pharmaceutical starting materials\(^2\)”, food and cosmetic standards as appropriate. EFPIA believes that it is not necessary to develop additional GMP guidelines for excipients.

EFPIA supports the use of excipient certification initiatives and shared / third party audit programmes of excipient suppliers as described the EFPIA position paper on Shared Audits. Participation in these programmes is at the discretion of the individual product manufacturer.

| Rationale | Alignment with the EFPIA objective to ensure better regulation i.e. effective legislation without unnecessary regulatory burden on manufacturers and suppliers to ensure continuity of supply of quality medicinal products for patients. |

---