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EU revives GMP for excipients

Direct link to the News/Story:-

The EFCEG has welcomed the addition of excipient GMP requirements to the draft amendments of the EU falsified medicines directive but warned that deeper analysis is needed to establish which products warrant further regulation.

A directive to establish good manufacturing practices (GMP) for certain excipients was dropped by the European Commission (EC) last year following concerns about the inflexibility of the proposal.

The issue is now back on the agenda after a draft opinion from the Committee on the Environment, Public Health and Food Safety (ENVI), the lead group for the anti-counterfeiting directive, proposed **GMP** requirements for excipients.

Broadly speaking this is a positive development, according to Alexandra Brand, a board member of the European Fine Chemicals Group (EFCEG). Speaking to in-PharmaTechnologist Brand said that "*patient safety is paramount*" and **excipient** quality is an important aspect of ensuring this.

However, the legislation must reflect the risk, added Brand. Some excipients are already appropriately regulated, according to Brand, and consequently GMP legislation covering all products "*would hammer on everyone when you only need to hit specific nails*"

To avoid this overlap in legislation, and the subsequent burden on excipient manufacturers, Brand is calling for a "*deeper analysis*" of the situation. This would identify which excipients need further legislation, such as those not covered by suitable food regulations.

Furthermore, GMP legislation covering excipients should differ from active pharmaceutical ingredients (API) regulations, Brand added. Again, this is to ensure that legislation ensures patient safety without subjecting excipient manufacturers to unnecessary burdens.

Currently, ENVI's draft opinion appears to lack these stipulations. It states: "*The manufacture of APIs or excipients should be subject to GMP irrespective of whether those ingredients or excipients were manufactured in the community or imported.*"

The EFCEG, and parent organisation the European Chemical Industry Council (Cefic), are now pushing to ensure the legislation takes its concerns into account. Currently, the EFCEG believes a final vote on the legislation is likely to occur in June.

Inspections

The draft opinion also states that routine or unannounced inspections of excipient manufacturers, importers or distributors should be conducted whenever there is a suspicion of non-compliance with GMP. This also covers unannounced inspections of sites outside the EU.

It is unclear if the final legislation will enforce mandatory inspections, with some questioning if there are sufficient resources. Regardless, the EFCG, in conjunction with groups including the International Pharmaceutical Excipients Council (IPEC), is pushing ahead with self-regulation.

The scheme would use third-party auditors to assess if excipient suppliers are in compliance with the certification standard the trade bodies have formulated. Brand hopes to have the programme in operation by the end of 2010.