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Press release

Brussels, 15 May 2019

The case for an Excipient Master File in Europe

The International Pharmaceutical Excipients Council Europe (IPEC Europe) released today a position paper and a Stimuli article to highlight how the absence of an Excipient Master File system in Europe is a barrier to the introduction of novel excipients and to innovation in the healthcare sector.

Novel excipients can play a pivotal role in the development of advanced drug delivery systems and enhance the quality and the safety of medicines for patients.

Currently, a novel excipient can only be introduced in Europe as part of the drug product marketing authorisation. This means that details on excipient quality, manufacturing and safety are shared with the drug product applicant.

“The absence of a functional and dedicated regulatory pathway for excipients”, said Frithjof Holtz, Chair of IPEC Europe, “hinders pharmaceutical product development, this is a commercial and administrative disadvantage facing novel excipient developers in Europe compared with other regions.”

IPEC Europe advocates for the introduction of an Excipient Master File system in Europe and calls on all European stakeholders to bridge this gap with other global markets.

This proposal builds upon experiences in other major regulatory environments – Japan, USA, Canada and China all rely on systems that allow an excipient manufacturer to submit the necessary details on their product to regulatory authorities without disclosing proprietary manufacturing information to third parties.

“A clear regulatory pathway that guarantees IP protection for novel excipient producers would encourage the development of innovative drug products, delivering increased access to better and safer medicines for European patients” said Holtz.

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