IPEC EUROPE POSITION PAPER ON THE NEED FOR AN EXCIPIENT MASTER FILE SYSTEM IN EUROPE

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Excipients are the inactive ingredients present in drug products. They play a critical role in the delivery of the active ingredient to the patient. They perform many functions in the drug product formulation and can be found in all dosage forms including parenteral, oral and topical applications.

Excipients are regulated as other drug product components and must meet stringent quality criteria which assures their purity. In addition, only excipients which have been assessed for patient safety are permitted to be used in drug product formulations. The assessment of safety to patients is rightly demanding and thorough details about the synthesis, testing and toxicological properties of the excipient are required, much of which is the intellectual property of the excipient supplier.

Once assessed for patient safety, then previously approved excipients can be more readily used in other drug product formulations, which reduces the regulatory burden for all parties concerned. This situation then perpetuates the use of the same set of excipients and acts as a deterrent to the introduction of new, i.e. novel, excipients.

Indeed, if you have just spent billions of dollars developing a new drug product then why increase the regulatory risks of refusal or delays by using a novel excipient which has never been used before? Drug product formulators will therefore always tend towards using the same existing range of excipients.

But new excipients can be introduced in drug products despite these hurdles. In much of the world, a Master File (MF) system that is open to excipients as well as active ingredients, allows an excipient manufacturer to submit the necessary quality, manufacturing and safety details on their product directly to the regulatory authorities thereby enabling protection of their intellectual property. However, in Europe in contrast to Japan, the USA, Canada and China, introducing a novel excipient can currently only be done through the drug product application. This means all these details, including proprietary manufacturing information, have to be shared with the drug product manufacturer.

Paradoxically, this is not the situation for the active ingredient. All these intellectual property details can be submitted separately to the authorities in a specific type of MF, namely an Active Substance Master File, with a small “open” section being shared with the drug product manufacturer. The absence of an EU excipient MF system is the last nail in the coffin for the introduction of new excipients in Europe.

Hence IPEC Europe has prepared a position paper to alert all stakeholders and the political processes of this deficiency which is effectively a total barrier to innovation in this vital sector of the economy with the objective to lobby for the introduction of an excipient MF system in Europe.