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PEGylation products, mono and combination therapies- Increasingly clearing regulatory hurdles and reaching market

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Originating as a novelty, PEGylation technology introduced by Davis and Abuchowski in the late 1970s, has undergone a shift from academic to industrial interest in recent years. The practical importance of the procedure is clearly demonstrated by the numbers of protein-PEG conjugates reaching the market or making it to an advanced state of clinical experimentation. Examples of commercialised products using PEGylation are Adagen®, Oncaspar®, PEGIntron®, PEGASYS®, Neulasta® and Somavert®, and a dozen other PEG-proteins which are now in advanced clinical trials. PEGylation, which started from protein modification, now includes delivery of oligonucleotides, genes, microparticles, liposomes and living cells and interferones. This continuing interest for new applications is well documented in over five hundred patents filed so far in the field, a situation which is not paralleled by any other polymer of pharmaceutical application. The success of PEG modification of proteins is, in a way, imitating nature's post transcriptional modification of proteins to expand and differentiate their role. It is probable that this strategy is not exclusive for poly ethylene glycol, as recent studies using polymers of natural origin such as polysaccharides and synthetic polymers have demonstrated.

The present review is focused on regulatory requirements related to innovation in field of PEG technology for delivery of bioactives and increasing use of such products as combination therapies to cover various possible ramifications of a disease. In case of PegIntron, on December 22, 2011, the Food and Drug Administration approved revisions to the product labeling for PegIntron to include the use of PegIntron with hepatitis C virus (HCV) NS3/4A protease inhibitors for the treatment of genotype 1, chronic hepatitis C (CHC) infection and in patients with neuropsychiatric disorders. The best way to use *PegIntron* in this indication is in combination with ribavirin in the form of Rebetol tablets. The combination dose titration may be an important issue, e,g., on May 8, 2009, FDA approved updates to the package insert for PegIntron combination product, adding a two-step dose reduction scheme for PegIntron and increasing the dose of Rebetol to 1200 mg/day for patients who weigh between 81 and 85 kilograms. Same is the case with other products. Oncaspar® is indicated as a component of a multi-agent chemotherapeutic regimen for the first line treatment of patients with ALL. These apart, for regulatory clearance, it is of prime importance that during the discovery phase the structure and PEGylation site, the PEG characteristics, the stability, the biological efficacy and duration are well defined. The developmental plan following the guidelines for both preclincal and clinical study should be related to the "innovation level" of the product.

Biography

Sandeep Arora, Director of Chitkara College of Pharmacy. He has a professional experience of around 16 years (3.5 years of Pharma Production and Quality Assurance and 16 years of Teaching/Training, and research) in the field of Pharmacognosy and Natural Products. He has to his credit editorial and authorship assignments as Hon. Editor – Advanced Drug Review (a quarterly drug pharmacology review index) since 2005, authored book titled "Pharmaceuticals- Issues for Industrial Management" and has 40 national and international research publications. He attended 20 conferences, out of which 4 are international. His area of specialization and research is medicinal natural products (phytochemical, pharmacological evaluation and standardization) and development and regulatory aspects of herbal and other products and industrial management.

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