CHARACTERISTICS AND POTENTIALBENEFITS OF THE RANIBIZUMABPRE-FILLED SYRINGE

Purpose:
Prefilled syringes (PFS) are one of thefastest growing classes of drug-delivery systems; inaddition to being convenient to use, they also mayhave the potential to reduce the risk of contamination.For intravitreal applications, the elimination of severalsteps during aseptic preparation may reduce the risk ofpotential iatrogenic eye infections that may result fromsuboptimal drug/device handling.

Methods: Characteristics, development process, andpotential benefits of ranibizumab PFS are described.

Results: The design features and functionality ofranibizumab PFS are as follows: 1) LUER lock closuresystem holding the needle tightly and enables needlechoice; 2) small syringe barrel (0.5 mL) with low voidvolume(fill volume: 0.165 mL); 3) unambiguous dosemark that facilitates high dose accuracy; 4) non-reactive borosilicate glass that provides storage stabil-ity; 5) non-retractable stopper to prevent inadvertentdrawing of non-sterile air and to minimize the poten-tial for sterility-related ocular adverse events; 6) spe-cially designed blister packaging that prevents thecontamination of sterile outer syringe surface. A baked‘silicone’ process is used for the development ofminimally-siliconized PFS. The barrel’s inner surface isspray-coated with silicon oil-in-water emulsion andsubsequently heat fixed. There were no relevant dif-ferences observed in product stability betweenranibizumab vials and the PFS.

Conclusions: The ranibizumab PFS aims to improvephysician convenience and efficiency of ranibizumabadministration in clinical practice with the potential toreduce risk of eye infection and saving time forpatients and physicians. Real time clinical practice datawill help demonstrate the advantages of ranibizumabPFS.