RANIBIZUMAB PRE-FILLED SYRINGE: RECENTLY APPROVED INNOVATION IN THE EUROPEAN UNION WITH THE POTENTIAL TO REDUCE INFECTION RISK, IMPROVE DOSE ACCURACY, AND ENHANCE EFFICIENT TREATMENT ADMINISTRATION

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Purpose: Ready-to-use injections eliminate aseptic preparation steps and reduce potential iatrogenic eye infection risks resulting from suboptimal drug and device handling. The ranibizumab pre-filled syringe (PFS) was specifically designed for single-use intraocular injection and approved recently in the European Union. Methods: Features, development process, and potential benefits of ranibizumab PFS are described. Results: Design features and functionality of ranibizumab PFS are as follows: LUER lock closure system holds the needle tightly and enables needle choice; small syringe barrel (0.5 mL) with low void volume; unambiguous dose mark facilitates high dose accuracy; and non-reactive borosilicate glass provides storage stability. The latex-free non-retractable plunger prevents inadvertent drawing of non-sterile air and minimizes the potential for sterility-related ocular adverse events. Specially designed blister packaging prevents the contamination of sterile outer syringe surface. Baked ‘silicone’ process was used for the development of minimally siliconized ranibizumab PFS. The barrel’s inner surface was spray-coated with silicon oil-in-water emulsion and subsequently heat-fixed. Minimal migration of silicon oil into the ranibizumab solution was observed with assessment by two orthogonal methods. No relevant differences were observed in product stability between ranibizumab vials and commercial syringes (e.g. when assessed using cation exchange chromatography). Ranibizumab PFS is easy to hold and may increase the efficiency of injection preparation by saving clinicians’ time, compared to conventional vial use. Conclusions: Ranibizumab PFS aims to improve overall efficiency of ranibizumab administration in clinical practice by offering potential for a reduced risk of eye infection, enhanced dose accuracy, and time savings for physicians and patients.