Claims

1. A terminally-sterilised syringe, the syringe ~~(1)~~ comprising a body (2), a stopper (10) and a plunger (4), the body ~~(2)~~ comprising an outlet (12) at an outlet end (14) and the stopper (10) being arranged within the body (2) such that a front surface (16) of the stopper (10) and the body (2) define a variable volume chamber (18) from which a fluid ~~(20)~~ can be expelled though the outlet (12), the plunger (4) comprising a plunger contact surface (22) at a first end (24) and a rod (26) extending between the plunger contact surface (22) and a rear portion (25);
wherein the variable volume chamber (18) is filled with medicament comprising an active suitable for the treatment of an ocular disease;
characterised in that:~~,~~
~~-~~the plunger contact surface (22) arranged to contact the stopper (10) but not couple thereto, such that the plunger (4) can be used to force the stopper (10) towards the outlet end (14) of the body (2), reducing the volume of the variable volume chamber (18), but not to move the stopper (10) away from the outlet end (14); and
~~characterised in that the rod comprises at least one rod shoulder directed away from the outlet end and the syringe includes a backstop arranged at a rear portion of the body, the backstop including a backstop shoulder directed towards the outlet end to cooperate with the rod shoulder to substantially prevent movement of the plunger rod away from the outlet end when the backstop shoulder and rod shoulder are in contact~~the syringe is dimensioned so as to have a nominal maximum volume of between 0.25 mL and 0.75 mL, or between 0.4 mL and 0.6 mL.

2. The syringe ~~as claimed in~~of claim 1, ~~in which the plunger contact surface (22) is a substantially planar disc and the plunger contact surface (22) contacts a rear surface (60) of the stopper (10)~~wherein the outlet (12) is reversibly sealed.

3. The syringe of any preceding claim, wherein the rod (26) comprises at least one rod shoulder (32) directed away from the outlet end (14) and the syringe includes a backstop arranged at a rear portion (25) of the body (2), the backstop including a backstop shoulder (34) directed towards the outlet end (14) to cooperate with the rod shoulder (32) to substantially prevent movement of the plunger rod (26) away from the outlet end (14) when the backstop shoulder (34) and rod shoulder (32) are in contact.

~~3~~4. The syringe ~~as claimed in~~of any ~~one of the~~ preceding claim~~s~~, ~~in which~~ wherein (a) the rod shoulder (32) is arranged within the external diameter of the rod (26); and/or (b) the rod shoulder (32) comprises a substantially disc shaped portion (46) on the rod (26), wherein the disc shaped portion (46) optionally includes gaps (50).

~~4. The syringe as claimed in any one of the preceding claims, in which the rod shoulder (32) comprises a substantially disc shaped portion on the rod (26).~~

5. The syringe ~~as claimed in any one of claims 1 to 4~~of claim 3 or claim 4, ~~in which~~ wherein the backstop ~~(6)~~ is removable from the syringe ~~(1)~~; and optionally wherein the backstop is configured to substantially sandwich terminal flanges (28) of the body.

~~6. The syringe as claimed in claim 5, in which the backstop (6) is configured to substantially sandwich terminal flanges of the body (2).~~

~~7~~6. The syringe ~~as claimed in~~ of any one of claims ~~1~~ 3 to ~~6~~5~~, in which~~ wherein, when arranged with the plunger contact surface (22) in contact with the stopper (10) and the variable volume chamber (18) is at its intended maximum volume, there is a clearance of no more than 2mm between the rod shoulder (~~34~~32) and backstop shoulder (~~32~~34).

~~8~~7. The syringe ~~as claimed in~~ of any ~~one of the~~ preceding claim~~s~~, ~~in which~~ wherein: (a) the variable volume chamber (18) has an ~~inner~~ internal diameter ~~of~~ between ~~4mm~~ 3 mm and ~~5mm~~6 mm; ~~.~~

~~9.~~ (b) ~~The syringe as claimed in any one of the preceding claims, in which~~ the syringe is dimensioned so as to have a nominal maximum fill volume of between ~~0.4ml~~ 0.4 mL and ~~0.6ml~~0.6 mL; ~~.~~ and/or (c) the length of the body (2) of the syringe is less than 70 mm, for instance less than 60 mm or less than 50 mm.

~~10. The syringe as claimed in any one of the preceding claims, in which the syringe is an ophthalmic syringe and the variable volume chamber is filled with an injectable medicament comprising a medicament suitable for the treatment of an ocular disease and the outlet is reversibly sealed.~~

8. The syringe of any preceding claim, wherein the length of the syringe body (2) is between 45 mm and 50 mm, the internal diameter is between 4mm and 5mm, and the fill volume is between 0.1 mL and 0.3 mL of liquid.

9. The syringe of any preceding claim, wherein: (a) the stopper (10) provides a sealing function by defining the rear of the variable volume chamber (18) with a fluid tight seal, which also provides a sterility seal; and/or (b) the stopper (10) contains one or more circumferential ribs *e.g.* three circumferential ribs (52, 54, 56).

10. The syringe of any preceding claim, wherein the stopper (10) contains at least a front circumferential rib (52) and a rear circumferential rib (56) which are separated in a direction along an axis (A) from the outlet end (14) to the rear end (38) by at least 3 mm.

11. The syringe of any preceding claim, wherein the plunger (4) which does not couple to the stopper (10) prevents a user from accidentally moving the plunger (4) and a stopper connected thereto (10) and causing non-sterile air or other fluid to be drawn into the syringe, or causing movement of the stopper (10) to a non-sterile area.

12. The syringe of any preceding claim, wherein: (a) the movement of the rod (26) away from the outlet end (14) is restricted; and/or (b) the plunger contact surface (22) is a substantially planar disc, and the plunger contact surface (22) contacts a rear surface of the stopper (10).

13. The syringe of any preceding claim, wherein (a) the body (2) is made out of a plastic material or glass and/or (b) the rod (26) is made from a plastic material.

14. The syringe of any preceding claim, wherein the syringe is silicone free or substantially silicone free.

15. The syringe of any one of claims 1-14, wherein the medicament comprises a biologic active which is an antibody (or fragment thereof) or a non-antibody protein.

16. The syringe of any one of claims 1-14, wherein the medicament comprises a VEGF antagonist.

17. The syringe of claim 16, wherein the VEGF antagonist is bevacizumab.

~~11~~18. A syringe pack comprising a sealed package and a sterile syringe ~~(1)~~ as ~~claimed~~ defined in any ~~one of the~~ preceding claim~~s~~.

19. A method of assembling a syringe according to any one of claims 1 to 17, the method comprising steps of:

(i) providing a body (2) and a stopper (10), the body comprising an outlet (12) at an outlet end (14) and the stopper (10) being arranged within the body (2) such that a front surface of the stopper (10) and the body (2) define a variable volume chamber (18) from which a fluid can be expelled though the outlet (12), the outlet being releasably sealed and the variable volume chamber (18) containing the injectable medicament; and

(ii) providing a plunger (4) comprising a plunger contact surface (22) at a first end (24) and a rod (26) extending between the plunger contact surface (22) and a rear portion and arranging the plunger contact surface (22) and at least part of the plunger (4) within the body (2) without coupling the plunger (4) to the stopper (10).

20. The method of claim 19, further comprising step (iii) filling the variable volume chamber of the syringe with the injectable medicament, wherein steps (ii) and (iii) may be

carried out in either order; and, optionally, wherein steps (i) and (iii) are carried out in a sterile, or substantially sterile, environment.

21. The method of claim 20, further comprising step (iv) packaging the assembled syringe in a substantially sealed package; and optionally, wherein, at some point between steps (iii) and (iv), the syringe is removed from the sterile, or substantially sterile, environment.

22. The method of claim 21, further comprising step (v) terminal sterilisation following packaging; for instance, wherein the terminal sterilisation step comprises Ethylene Oxide sterilisation or Hydrogen Peroxide sterilisation.