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Medicament delivery device

Abstract

A medicament delivery device includes: a body; a needle cover axially movable between an extended position and a retracted position; a medicament delivery mechanism including a plunger and a drive member configured to move the plunger to dispense a medicament; an actuation member configured to be actuated relative to the body; and a ratchet mechanism coupled to the medicament delivery mechanism and sequentially movable between a first configuration, second configuration and third configuration, wherein the actuation member and ratchet mechanism are arranged such that: a first actuation of the actuation member moves the ratchet mechanism from the first configuration to the second configuration to cause a first dose of the medicament to be dispensed, and a second actuation of the actuation member, subsequent to the first actuation, moves the ratchet mechanism from the second configuration to the third configuration to cause a second dose of the medicament to be dispensed.

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Background/Summary

TECHNICAL FIELD

(1) This application relates to a medicament delivery device for delivery of a medicament, a system comprising a medicament delivery device, and a method of using a medicament delivery device.

BACKGROUND

(2) Drug delivery devices such as auto-injectors are used to deliver a range of medicaments. In an

auto-injector device, some or all of the actions required to use the injector device in administering medicament are automated.

(3) An auto-injector device may have a needle cover which is axially movable to cover and uncover a needle, with the needle cover being biased by a spring to extend over the needle. Typically, the user presses the needle cover against an injection site, against the force of the spring, to push the needle cover into the housing and to uncover the needle which is pushed into the injection site. Medicament is automatically dispensed from the needle via an automated mechanism. A user must typically hold the needle cover in a holding position for a predetermined period of time, to ensure that the correct dose of medicament is dispensed from the device, before removing the device from the injection site.

(4) Some users may experience discomfort during the medicament delivery process. For example, some users may experience discomfort in the vicinity of the injection site when the delivered dose of medicament is large and/or delivered over a long period of time. If the discomfort becomes excessive, these users may decide to remove the auto-injector device from the injection site prematurely, which may result in incomplete delivery of the medicament dose, additional discomfort from premature withdrawal of the needle, and/or a wet injection site from leaked medicament.

(5) The present disclosure provides an injector device that addresses one or more of the problems mentioned above, and to provide an improved injector device.

SUMMARY

(6) A first aspect of this disclosure provides a medicament delivery device comprising: a body having a proximal end and a distal end, the body configured to hold a container containing a medicament; a needle cover axially movable relative to the body between an extended position and a retracted position; a medicament delivery mechanism comprising a plunger and a drive member, the drive member configured to move the plunger to dispense the medicament from the container; an actuation member configured to be actuated relative to the body; and a ratchet mechanism coupled to the medicament delivery mechanism and sequentially movable between a first configuration, a second configuration and a third configuration, wherein the actuation member and the ratchet mechanism are arranged such that: a first actuation of the actuation member moves the ratchet mechanism from the first configuration to the second configuration to cause a first dose of the medicament to be dispensed, and a second actuation of the actuation member, subsequent to the first actuation, moves the ratchet mechanism from the second configuration to the third configuration to cause a second dose of the medicament to be dispensed.

(7) The actuation member may comprise a button arranged to be pushed a first time to provide the first actuation and pushed a second time to provide the second actuation.

(8) The actuation member may be movable between a first position and a second position, wherein the first actuation of the actuation member comprises a first movement of the actuation member from the first position to the second position, and wherein the second actuation of the actuation member comprises a second movement of the actuation member from the first position to the second position, the second movement subsequent to the first movement.

(9) The ratchet mechanism may comprise: a ratchet shuttle axially movable by the drive member and comprising a protrusion; and an engagement track comprising a first engagement element and a second engagement element, wherein the protrusion is configured to engage the first engagement element when the ratchet mechanism is in the first configuration, to limit axial movement of the ratchet shuttle by the drive member.

(10) The protrusion may be configured to engage the second engagement element when the ratchet mechanism is in the second configuration, to limit axial movement of the ratchet shuttle by the drive member.

(11) The arm may comprise a plurality of apertures and a plurality of guide surfaces arranged such that the apertures and guide surfaces alternate in an axial direction.

(12) The ratchet shuttle may be a ratchet collar.
(13) The actuation member and ratchet mechanism may be configured such that: the first actuation of the actuation member disengages the protrusion from the first engagement element to cause the protrusion to move axially to the second engagement element; and the second actuation of the actuation member disengages the protrusion from the second engagement element to cause the protrusion to move axially.
(14) The medicament delivery device may further comprise a needle cover axially movable relative to the body between an extended position, in which a distal end of the needle cover is distal to a distal end of a needle, and a retracted position, in which the distal end of the needle is distal to the distal end of the needle cover.
(15) The medicament delivery device may further comprise a needle cover biasing member configured to bias the needle cover distally.
(16) The medicament delivery device may further comprise a needle cover guide having a track configured to be engaged by a guide protrusion of the needle cover such that an axial movement of the needle cover from the extended position to the retracted position causes a rotation of the needle cover guide relative to the needle cover.
(17) The track may comprise a locking element arranged such that an axial movement of the needle cover from the retracted position to the extended position subsequent to the rotation of the needle cover guide engages the guide protrusion with the locking element, to limit a further axial movement of the needle cover from the extended position to the retracted position.
(18) The medicament delivery device may be configured such that a further rotation of the needle cover guide relative to the needle cover disengages the guide protrusion from the locking element to allow the further axial movement of the needle cover from the extended position to the retracted position.
(19) The medicament delivery device may be configured to be releasably coupled to a needle unit comprising a needle, wherein the needle cover guide is configured such that the further rotation is performed as the needle unit is coupled or uncoupled from the medicament delivery device by a needle unit tool releasably coupled to the needle cover guide.
(20) The medicament delivery device of may further comprise an actuation member latch movable between a locked configuration, in which actuation of the actuation member is limited, and an unlocked configuration, in which actuation of the actuation member is allowed.
(21) The actuation member latch may be configured to be moved from the locked configuration to the unlocked configuration by movement of the needle cover from the extended position to the retracted position.
(22) The actuation member and the ratchet mechanism may be arranged such that: a third actuation of the actuation member moves the ratchet mechanism from the third configuration to a fourth configuration to cause a third dose of the medicament to be dispensed.
(23) The medicament delivery device may further comprise the medicament.
(24) A second aspect of this disclosure provides a system comprising: a medicament delivery device as disclosed herein; a needle unit releasably couplable to the medicament delivery device; and a needle unit tool for coupling the needle unit to the medicament delivery device or uncoupling the needle unit from the medicament delivery device.
(25) A third aspect of this disclosure provides a method of operating a medicament delivery device as disclosed herein, the method comprising: actuating the actuation member of the medicament delivery device to dispense a first dose of the medicament; and subsequent to actuating the actuation member of the medicament delivery device to dispense the first dose of the medicament, actuating the actuation member of the medicament delivery device to dispense a second dose of medicament.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

(1) Exemplary embodiments of the present disclosure are described with reference to the accompanying drawings, in which:

(2) FIG. **1**A shows an injector device with a cap attached;

(3) FIG. **1**B shows the injector device of FIG. **1**A with the cap removed;

(4) FIG. **2** is a cross-sectional view of a medicament delivery device;

(5) FIG. **3**A is a schematic cross-sectional view of a medicament delivery device in accordance with one or more embodiments, in a first state;

(6) FIG. **3**B is a schematic cross-sectional view of the medicament delivery device of FIG. **3**A, in a second state;

(7) FIG. **3**C is a schematic cross-sectional view of the medicament delivery device of FIG. **3**B, in a third state;

(8) FIG. **3**D is a schematic cross-sectional view of the medicament delivery device of FIG. **3**C, in a fourth state;

(9) FIG. **3**E is a schematic cross-sectional view of the medicament delivery device of FIG. **3**D, in a fifth state;

(10) FIG. **3**F is a schematic cross-sectional view of the medicament delivery device of FIG. **3**E, in a sixth state;

(11) FIG. **3**G is a schematic cross-sectional view of the medicament delivery device of FIG. **3**F, in a seventh state;

(12) FIG. **3**H is a schematic cross-sectional view of the medicament delivery device of FIG. **3**G, in an eighth state;

(13) FIG. **3**I is a schematic cross-sectional view of the medicament delivery device of FIG. **3**H, in a ninth state;

(14) FIG. **3**J is a schematic cross-sectional view of the medicament delivery device of FIG. **3**I, in a tenth state;

(15) FIG. **3**K is a schematic cross-sectional view of the medicament delivery device of FIG. **3**J, in an eleventh state;

(16) FIG. **4**A is a schematic cross-sectional view of a portion of a medicament delivery device in accordance with one or more embodiments, showing an actuation member latch in a locked configuration and an actuation member in a first position;

(17) FIG. **4**B is a schematic cross-sectional view of a portion of the medicament delivery device of FIG. **4**A showing actuation member latch in an unlocked configuration and the actuation member in the first position;

(18) FIG. **4**C is a schematic cross-sectional view of a portion of the medicament delivery device of FIG. **4**B, showing actuation member latch in the unlocked configuration and the actuation member in a second position;

(19) FIG. **5**A is a cross-sectional perspective view of a portion of a medicament delivery device in accordance with one or more embodiments, prior to dispensing a first dose of medicament;

(20) FIG. **5**B is a cross-sectional perspective view of a portion of the medicament delivery device of FIG. **5**A, during initiation of the dispensing of the first dose of medicament;

(21) FIG. **5**C is a cross-sectional perspective view of a portion of the medicament delivery device of FIG. **5**B, after dispensing of the first dose of medicament, and prior to dispensing a second dose of medicament;

(22) FIG. **5**D is a cross-sectional perspective view of a portion of the medicament delivery device of FIG. **5**C, during initiation of the dispensing of the second dose of medicament;

(23) FIG. **5**E is a cross-sectional perspective view of a portion of the medicament delivery device

of FIG. **5**D, after dispensing of the second dose of medicament, and prior to dispensing a third dose of medicament;
(24) FIG. **5**F is a cross-sectional perspective view of a portion of the medicament delivery device of FIG. **5**E, during dispensing of the third dose of medicament;
(25) FIG. **5**G is a cross-sectional perspective view of a portion of the medicament delivery device of FIG. **5**F, after dispensing of the third dose of medicament;
(26) FIG. **6**A is a perspective view of a needle cover guide and portion of a needle cover of the medicament delivery device of FIG. **3**A;
(27) FIG. **6**B is a perspective view of a needle cover guide and portion of a needle cover of the medicament delivery device of FIG. **3**B;
(28) FIG. **6**C is a perspective view of a needle cover guide and portion of a needle cover of the medicament delivery device of FIG. **3**E;
(29) FIG. **6**D is a perspective view of a needle cover guide and portion of a needle cover of the medicament delivery device of FIG. **3**F, after coupling of a needle unit tool;
(30) FIG. **6**E is a perspective view of a needle cover guide and portion of a needle cover of the medicament delivery device of FIG. **3**G;
(31) FIG. **6**F is a perspective view of a needle cover guide and portion of a needle cover of the medicament delivery device of FIG. **3**K;
(32) FIG. **7** is a perspective view of a needle cover guide, a needle unit tool and a portion of a needle cover, in accordance with one or more embodiments; and
(33) FIG. **8** is a flowchart illustrating a method of using a medicament delivery device in accordance with one or more embodiments.

DETAILED DESCRIPTION

(34) One or more aspects of the present disclosure may provide a medicament delivery device configured to dispense a medicament in a plurality of discrete doses, a system comprising a medicament delivery device configured to dispense a medicament in a plurality of discrete doses, and a method of using a medicament delivery device configured to dispense a medicament in a plurality of discrete doses.
(35) A drug delivery device (also referred to as a medicament delivery device), as described herein, may be configured to inject a medicament into a subject (e.g., a patient). For example, delivery could be sub-cutaneous, intra-muscular, or intravenous. Such a device could be operated by the subject themselves (i.e., ‘self-administration’) or by a different user, such as a nurse or physician providing care to the subject, and can include various types of safety syringe, pen-injector, or auto-injector. The device can include a cartridge-based system that requires piercing a sealed ampule before use. Volumes of medicament delivered with these various devices can range from about 0.5 ml to about 2 ml (e.g., to about 2.25 ml). Yet another device can include a large volume device (“LVD”) or patch pump (in some instances referred to as an on body injector (OBI) or on body device (OBD)), configured to adhere to a subject's skin for a period of time (e.g., about 5, 15, 30, 60, or 120 minutes) to deliver a “large” volume of medicament (typically about 2 ml to about 10 ml, or about 2 mL to about 20 mL).
(36) In combination with a specific medicament, the presently described devices may also be customized in order to operate within required specifications. For example, the device may be customized to inject a medicament within a certain time period (e.g., about 3 to about 20 seconds for auto-injectors, and about 10 minutes to about 60 minutes for an LVD). Other specifications can include a low or minimal level of discomfort, or to certain conditions related to human factors, shelf-life, expiry, biocompatibility, environmental considerations, etc. Such variations can arise due to various factors, such as, for example, a drug ranging in viscosity from about 3 cP to about 50 cP. Consequently, a drug delivery device will often include a hollow needle ranging from about 25 to about 31 Gauge in size. Common sizes are 27 and 29 Gauge.
(37) The delivery devices described herein can also include one or more automated functions. For

example, one or more of needle insertion, medicament injection, and needle retraction can be automated. Energy for one or more automation steps can be provided by one or more energy sources. Energy sources can include, for example, mechanical, pneumatic, chemical, or electrical energy. For example, mechanical energy sources can include springs, levers, elastomers, or other mechanical mechanisms to store or release energy. One or more energy sources can be combined into a single device. Devices can further include gears, valves, or other mechanisms to convert energy into movement of one or more components of a device.

(38) The one or more automated functions of an auto-injector may each be activated via an activation mechanism. Such an activation mechanism can include one or more of a button, a lever, a needle sleeve (also referred to as a needle cover), or other activation component. Activation of an automated function may be a one-step or multi-step process. That is, a user may need to activate one or more activation components in order to cause the automated function. For example, in a one-step process, a user may depress a needle sleeve against their body in order to cause injection of a medicament. Other devices may require a multi-step activation of an automated function. For example, a user may be required to depress a button and retract a needle sleeve in order to cause injection.

(39) In addition, activation of one automated function may activate one or more subsequent automated functions, thereby forming an activation sequence. For example, activation of a first automated function may activate at least two of needle insertion, medicament injection, and needle retraction. Some devices may also require a specific sequence of steps to cause the one or more automated functions to occur. Other devices may operate with a sequence of independent steps.

(40) Some delivery devices can include one or more functions of a safety syringe, pen-injector, or auto-injector. For example, a delivery device could include a mechanical energy source configured to automatically inject a medicament (as typically found in an auto-injector) and a dose setting mechanism (as typically found in a pen-injector).

(41) According to some embodiments of the present disclosure, an exemplary drug delivery device **10** is shown in FIGS. **1**A & **1**B. Device **10**, as described above, is configured to inject a medicament **15** into a subject's body. Device **10** includes a housing **11**, which may also be referred to as a body, which typically contains a reservoir **14** containing the medicament **15** to be injected (e.g., a syringe) and the components required to facilitate one or more steps of the delivery process. Device **10** can also include a cap assembly **12** that can be detachably mounted to the housing **11**. Typically, a user must remove cap **12** from housing **11** before device **10** can be operated. Device **10** can include a window **11***a* through which a user may view medicament **15** remaining in the reservoir **14**.

(42) As shown, housing **11** is substantially cylindrical and has a substantially constant diameter along the longitudinal axis X. The housing **11** has a distal region **20** and a proximal region **21**. The term “distal” refers to a location that is relatively closer to a site of injection, and the term “proximal” refers to a location that is relatively further away from the injection site.

(43) Device **10** can also include a needle sleeve **13** coupled to housing **11** to permit movement of the needle sleeve **13** relative to housing **11**. For example, needle sleeve **13** can move in a longitudinal direction parallel to longitudinal axis X. Specifically, movement of needle sleeve **13** in a proximal direction can permit a needle **17** to extend from distal region **20** of housing **11**.

(44) Insertion of needle **17** can occur via several mechanisms. For example, needle **17** may be fixedly located relative to housing **11** and initially be located within an extended needle sleeve **13**. Proximal movement of needle sleeve **13** by placing a distal end of sleeve **13** against a subject's body and moving housing **11** in a distal direction will uncover the distal end of the needle **17**. Such relative movement allows the distal end of the needle **17** to extend into the injection site, such as a portion of the subject's body. Such insertion is termed “manual” insertion as needle **17** is manually inserted via the subject's manual movement of housing **11** relative to the needle sleeve **13**.

(45) Another form of insertion is “automated,” whereby the needle **17** moves relative to housing **11**.

Such insertion can be triggered by movement of the needle sleeve **13** or by another form of activation, such as, for example, a button **22**. As shown in FIGS. **1**A & **1**B, the button **22** is located at a proximal end of housing **11**. However, in other embodiments, the button **22** could be located on a side of housing **11**.

(46) Other manual or automated features can include drug injection or needle retraction, or both. Injection is the process by which a bung or piston **23** is moved from a proximal location within a syringe (not shown in FIGS. **1**A and **1**B) to a more distal location within the syringe in order to force a medicament **15** from the syringe through needle **17**. In some embodiments, a biasing member such as a drive spring (not shown in FIGS. **1**A and **1**B) is under compression before device **10** is activated. A proximal end of the drive spring can be fixed within proximal region **21** of housing **11**, and a distal end of the drive spring can be configured to apply a compressive force to a proximal surface of piston **23**. Following activation, at least part of the energy stored in the drive spring can be applied to the proximal surface of piston **23**. This compressive force can act on piston **23** to move it in a distal direction. Such distal movement acts to compress the liquid medicament **15** within the syringe, forcing it out of needle **17**.

(47) Following injection, needle **17** can be retracted within the needle sleeve **13** or housing **11**. Retraction can occur when the needle sleeve **13** moves distally as a user removes device **10** from a subject's body. This can occur as needle **17** remains fixedly located relative to housing **11**. Once a distal end of sleeve **13** has moved past a distal end of needle **17**, and needle **17** is covered, sleeve **13** can be locked. Such locking can include locking any proximal movement of sleeve **13** relative to housing **11**.

(48) Another form of needle retraction can occur if needle **17** is moved relative to housing **11**. Such movement can occur if the syringe within housing **11** is moved in a proximal direction relative to housing **11**. This proximal movement can be achieved by using a retraction spring (not shown), located in distal region **20**. A compressed retraction spring, when activated, can supply sufficient force to the syringe to move it in a proximal direction. Following sufficient retraction, any relative movement between needle **17** and housing **11** can be locked with a locking mechanism. In addition, button **22** or other components of device **10** can be locked as required.

(49) FIG. **2** shows a simplified view of a medicament delivery device **100** that extends along an axis **144**. The medicament delivery device **100** may share one or more features with the drug delivery device **10** discussed in relation to FIGS. **1**A and **1**B.

(50) The medicament delivery device **100** may be configured to inject greater than 2 ml of medicament and/or the medicament delivery device **100** may be configured to inject medicament having a viscosity of greater than 25 cP. Nevertheless, in other examples the medicament delivery device **100** may be configured to inject 2 ml or less of medicament and/or the medicament delivery device **100** may be configured to inject medicament having a viscosity of 25 cP or less.

(51) The medicament delivery device **100** has a body **111** having a proximal end **130** and a distal end **131** arranged along the axis **144**, a hollow needle **117** for injecting medicament **115**, and a needle cover **113**. The body **111** is shown to be substantially cylindrical, however it should be understood that the body **111** may have a different shape in other examples.

(52) The body **111** houses a pre-filled syringe **150**, which comprises a container **114** containing the medicament **115**. The needle **117** is coupled to a distal end of the container **114** and is in fluid communication with an interior of the container **114** such that the medicament **115** may be dispensed from the container **114**, via the needle **117**. FIG. **2** shows the needle **117** permanently coupled to the container **114**, however it should be understood that this is not meant to be limiting. For example, in other instances, the needle **117** may be removably couplable to the container **114** (e.g., via a Luer lock interface between a connector on the container **114** and a connector coupled to the needle **117**) such that the needle **117** may be coupled to the container **114** prior to an injection and uncoupled from the container **114** after an injection (e.g., to replace the needle **117** with a new needle **117**).

(53) The syringe **150** further comprises a bung or piston **123** arranged within the container **114**, proximal to the medicament **115** and the needle **117**. The piston **123** is arranged within the container **114** to be moved distally to force the medicament **115** out of the container **114**, via the needle **117**.
(54) The needle **117** has a distal end **140**. The needle cover **113** is proximally movable relative to the body **111** between an extended position, in which the needle cover **113** covers the distal end **140** of the needle **117**, and a retracted position, in which the distal end **140** of the needle **117** protrudes from the needle cover **113** for penetration into an injection site. FIG. **2** shows the device **100** with the needle cover **113** in the extended position. The medicament delivery device **100** further comprises a needle cover biasing member **118**, such as a spring, configured to bias the needle cover **113** axially in the distal direction. The distal direction is indicated by the direction of the arrow **152** in FIG. **2**.
(55) The medicament delivery device **100** comprises a medicament delivery mechanism **180** for dispensing the medicament **115** from the syringe **150** held within the body **111**. The medicament delivery mechanism **180** comprises a plunger **121**, a rotary collar **119** and a drive member **124**.
(56) The plunger **121**, which may be coaxial with the axis **144**, is axially movable within the syringe **150** of the device **100** in a distal direction to dispense the medicament **115** from the syringe **150** via the needle **117**. The plunger **121** is arranged to engage the piston **123** of the syringe **150** such that distal axial movement of the plunger **121** moves the piston **123** distally to dispense the medicament **115** via the needle **117**.
(57) The rotary collar **119**, which may also be coaxial with the axis **144**, is axially fixed relative to the body **111** but is rotatable within the body **111** (e.g., about the axis **144**). The drive member **124** is configured to rotate the rotary collar **119** when the drive member **124** is actuated/released. For example, the drive member **124** may be a spring (e.g., a torsion spring), wherein the spring is configured to rotate the rotary collar **119** when the spring is released. However, it should be understood that one or more other types of drive member **124** may be used instead, such as a pneumatic drive member. The drive member **124** is released when the needle cover **113** reaches a predetermined axial displacement with respect to the body **111**.
(58) The rotary collar **119** and the plunger **121** are arranged such that the rotation of the rotary collar **119** by the drive member **124** causes the plunger **121** to move distally within the syringe **150**, to thereby dispense the medicament **115** from the syringe **150** via the needle **117**. For example, the plunger **121** may comprise an external screw thread **122** that is configured to interface with an internal screw thread of the rotary collar **119** such that rotation of the rotary collar **119** causes distal translation of the plunger **121**. However, it should be understood that other forms of interface between the rotary collar **119** and the plunger **121** for converting rotation of the rotary collar **119** into translation of the plunger **121** may be used instead. For example, in other instances, only one of the rotary collar **119** and the plunger **121** may have a screw thread, and the other of the rotary collar **119** and the plunger **121** may have one or more engagement features, such as one or more projections, that are arranged to engage with the screw thread such that rotation of the rotary collar **119** causes translation of the plunger **121**.
(59) To initiate delivery of the medicament **115** into a subject (who may be the user of the medicament delivery device **100**, a different person to the user of the device, or an non-human animal), a distal end **120** of the needle cover **113** is to be pressed against the injection site on the subject and the body **111** is moved towards the injection site, thereby moving the needle cover **113** axially into the body **111** and uncovering the needle **117** from within the needle cover **113** such that it penetrates the injection site. The proximal axial displacement of the needle cover **113** causes the release of the drive member **124**, which rotates the rotary collar **119**. The rotation of the rotary collar **119** moves the plunger **121** axially within the syringe **150** to dispense the medicament **115** into the injection site via the needle **117**. The device **100** is pressed against the injection site to hold the needle cover **113** in its retracted position whilst the medicament **115** is dispensed from the

device **100**.
(60) After the medicament **115** has been dispensed, the device **100** is removed from the injection site by moving the body **111** away from the injection site. In doing so, the needle cover **113** moves distally under the force of the biasing member **118** towards the extended position to cover the distal end **140** of the needle **117** and therefore protect the user and/or subject from an accidental needle-stick event. In some instances, subsequent proximal movement of the needle cover **113** relative to the body **111** may be inhibited by a locking mechanism.
(61) FIGS. **3**A to **3**K show a schematic cross-section view of a medicament delivery device **200** (which may be an auto-injector) in various stages of operation, in accordance with one or more aspects of the present disclosure.
(62) The features described and/or contemplated in relation to the medicament delivery device **200** may be incorporated in the medicament delivery device **100** described and/or contemplated above in relation to FIG. **2**. Alternatively, or additionally, the features described and/or contemplated in relation to the medicament delivery device **200** may be incorporated in another medicament delivery device, for example a medicament delivery device having a different mechanism for dispensing a medicament to that described in relation to the medicament delivery device **100**. Like references refer to like features.
(63) With reference to FIG. **3**A, the medicament delivery device **200** includes a body **111**, also referred to as a housing, extending along an axis **144** of the medicament delivery device **200** and having a proximal end **130** and a distal end **131**. The body **111** is substantially cylindrical, however this is not meant to be limiting, and it should be understood that other shapes may be envisaged for the body **111** that are not cylindrical. A syringe **150** comprising a container **114** containing a medicament **115** is held within the body **111**.
(64) The medicament delivery device **200** includes a needle unit **116** that is releasably couplable to the syringe **150** such that it can be coupled to the syringe **150** and uncoupled from the syringe **150** by a user. The needle unit **116** comprises a hollow needle **117** for injecting the medicament **115** and a connection interface **141** configured to releasably couple to a corresponding connection interface **142** of the syringe **150**. When the needle unit **116** is coupled to syringe **150**, the needle **117** is in fluid communication with the container **114** such that medicament **115** may be dispensed from the container **114** via the needle **117**.
(65) In some examples, a distal end of the container **114** may be sealed by a septum that is configured to be pierced by a proximal end of the needle **117** (or a different needle of the needle unit **116** that is in fluid communication with the needle **117**) to bring the needle **117** into fluid communication with the medicament **115** within the container **114**. However, it should be noted that in other examples, no pierceable septum is used (e.g., since the medicament **115** is prevented from leaving the container **114** prior to connection of the needle unit **116** by surface tension of the medicament **115** and/or pressure differentials).
(66) Various alternative mechanisms for connecting the needle unit **116** and the syringe **150** may be employed. For example, in some examples, the connection interface **141** and connection interface **142** may be configured to provide a screw connection, wherein the needle unit **116** is configured to be screwed onto the connection interface **142** to couple the needle unit **116** to the syringe **150** and/or wherein the needle unit **116** is configured to be unscrewed from the connection interface **142** to uncouple the needle unit **116** from the syringe **150**. To screw the needle unit **116** onto the connection interface **142**, the screw-type connection interface **141** of the needle **116** is brought into engagement with the screw-type connection interface **142** of the syringe **150** by simultaneous rotation (e.g., about axis **144**) and proximal translation of the needle unit **116** relative to the medicament delivery device **200** (e.g., relative to the syringe **150**). To unscrew the needle unit **116** from the connection interface **142**, the screw-type connection interface **141** of the needle **116** is brought out of engagement with the screw-type connection interface **142** of the syringe **150** by rotation of the needle unit **116** in an opposite direction to the direction used to couple the needle

unit **116** and the syringe **150**, simultaneous with distal translation of the needle unit **116** relative to the medicament delivery device **200** (e.g., relative to the syringe **150**). As an example, of a screw-type connection, the connection interface **141** and connection interface **142** may provide a Luer lock connection when coupled, with the connection interface **141** comprising one of a male or female Luer lock connector and the connection interface **142** comprising the other of a male or female Luer lock connector.

(67) In additional or alternative examples, the needle unit **116** may be configured to be coupled and/or uncoupled from the syringe **150** using a snap-fit connection. For example, to couple the needle unit **116** to the connection interface **142**, a snap-fit connection interface **141** of the needle unit **116** may be moved axially relative to the medicament delivery device **200** and syringe **150**, in the proximal direction, until the snap-fit connection interface **141** of the needle unit **116** engages a snap-fit connection interface **142** of the syringe **150**. The relative axial movement is continued until the snap-fit connection between the connection interface **141** of the needle unit and the connection interface **142** of the syringe **150** is formed, at which point the needle unit **116** is coupled to the syringe **150**. To uncouple the needle unit **116** from the connection interface **142**, a snap-fit connection interface **141** of the needle unit may be moved axially relative to the medicament delivery device **200** and syringe **150**, in the distal direction, until a coupling force between the snap-fit connection interface **141** of the needle unit **116** and the snap-fit connection interface **142** is overcome, separating the needle unit **116** from the syringe **150**.

(68) It should be noted that in some examples, the needle unit **116** may be configured to couple to the syringe connection interface **142** using a different mechanism to the mechanism used for uncoupling the needle unit **116** from the syringe connection interface **142**. For example, in some examples the connection interface **141** of the needle unit **116** and the connection interface **142** of the syringe **150** may be configured to be coupled together by a snap-fit connection (e.g. by axially bringing the connection interfaces **141**, **142** together, in some cases without relative rotation), but uncoupled by unscrewing the connection interface **141** from the connection interface **142**. In other examples, the connection interface **141** of the needle unit **116** and the connection interface **142** of the syringe **150** may be configured to be coupled together by a screwing the connection interfaces **141**, **142** together, but uncoupled by axially separating the connection interface **141** from the connection interface **142** (e.g., as described in relation to the snap-fit connection, in some examples without relative rotation between the connection interfaces **141**, **142**).

(69) Additionally or alternatively, other types of connection between the connection interfaces **141**, **142** may be employed such as a bayonet connection (in which the relative axial and then rotational movement is used to connect the connection interfaces **141**, **142**, and then relative rotational and then axial movements in the opposite directions are used to uncouple the connection interfaces **141**, **142**), or a friction-fit connection (e.g., a Luer slip connection) which employs relative axial movement to couple and/or uncouple the connection interfaces **141**, **142** (optionally in combination with relative rotation). Again, in some examples, a different mechanism for coupling the connection interfaces **141**, **142** compared to uncoupling the connection interfaces **141**, **142** may be used (e.g., the connection interfaces **141**, **142** may be coupled by a snap-fit connection but uncoupled by a bayonet connection).

(70) The various types of connections and/or combinations of connection types disclosed herein are not meant to be limiting, and it should be envisaged that other types of connections and/or combinations of connection types may be employed with aspects of the present disclosure.

(71) The needle unit **116** can be uncoupled from the medicament delivery device **200** and replaced by another needle unit **116** between injections, for example using one or more needle unit tools, as described later.

(72) As shown in FIG. **3**A, the medicament delivery device **200** includes a needle cover **113** axially movable relative to the body **111** between an extended position and a retracted position. When the needle cover **113** is in the extended position and the needle unit **116** is coupled to the medicament

delivery device **200**, the needle cover **113** extends from the distal end **131** of the body **111** such that a distal end **140** of the needle **117** is surrounded, to protect a user from an accidental needle-stick injury prior to an actual injection. When the needle cover **113** is in the retracted position and the needle unit **116** is coupled to the medicament delivery device **200**, the distal end **140** of the needle **117** protrudes distally from the distal end **120** of the needle cover **113** such that the distal end **140** of the needle **117** can penetrate an injection site.

(73) A needle cover biasing member **118**, which in this example takes the form of a spring, is configured to bias the needle cover **113** distally, from the retracted position to the extended position. It should be understood that in other examples the needle cover biasing member **118** may take a different form to a spring, for example a pneumatic mechanism or an elastic polymer.

(74) In FIG. **3**A, the medicament delivery device **200** is shown in a first state prior to an injection, in which the medicament delivery device **200** is not being held against an injection site. The needle cover **113** is in the extended position with respect to the body **111**, biased into the extended position by the needle cover biasing member **118**. The needle cover **113** is axially movable relative to the body **111** between the extended position shown in FIG. **3**A, in which a distal end **120** of the needle cover **113** is distal to a distal end **140** of the needle **117**, and the retracted position shown in FIG. **3**B, in which the distal end **140** of the needle **117** is distal to the distal end **120** of the needle cover **113**.

(75) The medicament delivery device **200** comprises a medicament delivery mechanism **180** for dispensing the medicament **115** from the syringe **150** held within the body **111**. The medicament delivery mechanism **180** in this example comprises a plunger **121**, a rotary collar **119** and a drive member such as a spring (e.g., torsion spring), one or more of which may be as described above in relation to the device **100**. However, it should be understood that in other examples, the medicament delivery mechanism **180** may comprise one or more different components than a plunger **121**, a rotary collar **119** and/or drive member. The drive member is hidden in FIGS. **3**A-**3**K, but may be arranged to at least partially surround the rotary collar **119**.

(76) The plunger **121**, which may be coaxial with the axis **144**, is axially movable within the syringe **150** of the medicament delivery device **200** to dispense medicament **115** from the syringe **150** via the needle **117**. The plunger **121** is located proximal to a piston **123** of the syringe **150**. FIG. **3**A shows that the distal end of the plunger **121** is initially axially separated from the piston **123** when the medicament delivery device **200** is in its first state. However, it should be understood that in other examples the distal end of the plunger **121** may be engaged with the piston **123** when the medicament delivery device **200** is in its first state.

(77) The rotary collar **119**, which may be coaxial with the axis **144**, is axially fixed relative to the body **111** but is able to rotate with respect to the body **111** (e.g., about the axis **144**). The drive member is configured to rotate the rotary collar **119** when released, to move the plunger **121** to dispense the medicament **115** from the container **114**. The drive member may be a spring such as a torsion spring, however other forms of spring/drive member may be used instead.

(78) The rotary collar **119** interfaces with the plunger **121** (e.g. via any of the interfaces previously described in relation to FIG. **2**, such as an internal screw thread **125** of the rotary collar **119** interfacing with an external screw thread **122** of the plunger **121**) such that the rotation of the rotary collar **119** by the drive member causes the plunger **121** to move distally within the syringe **150** to thereby dispense medicament **115** from the syringe **150** via the needle **117** (e.g., in the same or similar manner as previously described in relation to FIG. **2**).

(79) The medicament delivery device **200** further comprises an actuation member **404**, an actuation member latch **450**, and a ratchet mechanism **505**. Aspects of the actuation member **404** and the ratchet mechanism **505** are also described in relation to FIGS. **5**A-**5**G, which are schematic cross-sections of a proximal end of a medicament delivery device **500**, which may share one or more features of the medicament delivery device **200** described in relation to FIGS. **3**A-**3**K. Some features of the medicament delivery **200** device shown in FIGS. **3**A-**3**K such as the spring **171** and

the actuation member latch **450** are hidden in FIGS. **5**A-**5**G for clarity.
(80) The ratchet mechanism **505** is coupled to the medicament delivery mechanism **180** and is configured for causing the medicament delivery mechanism **180** to dispense the medicament **115** in a plurality of discrete, predefined doses. The ratchet mechanism **505** is configured to be sequentially moved between a plurality of configurations, wherein movement of the ratchet mechanism **505** between each configuration causes the medicament delivery mechanism **180** to dispense a respective dose of medicament **115** of the plurality of doses. The ratchet mechanism **505** comprises at least a first configuration, a second configuration and a third configuration, wherein movement of the ratchet mechanism **505** from the first configuration to the second configuration causes a first dose of the medicament **115** to be dispensed, and wherein subsequent movement of the ratchet mechanism **505** from the second configuration to the third configuration causes a second dose of the medicament **115** to be dispensed. If the ratchet mechanism **505** comprises a fourth configuration, then subsequent movement of the ratchet mechanism **505** from the third configuration to the fourth configuration may cause a third dose of the medicament **115** to be dispensed (with subsequent movement to a fifth configuration, if present, causing a fourth dose to be dispensed etc.).
(81) As shown in FIG. **3**A and FIG. **5**A, the ratchet mechanism **505** comprises a plurality of engagement elements **540** and an axially movable ratchet shuttle, in this example the ratchet shuttle being in the form of a ratchet collar **510**.
(82) The ratchet collar **510** is arranged within the body **111** to at least partially surround and engage the rotary collar **119**. The ratchet collar **510** may be configured to move axially within respect to the body **111** and the rotary collar **119**, but may be inhibiting from rotating relative to the body **111** and rotary collar **119**, for example due to interaction with an axial guide (not shown). An interface between the ratchet collar **510** and the rotary collar **119** (e.g. a screw thread interface, similar to a screw thread interface previously described in relation to FIG. **2**) is configured such that rotation of the rotary collar **119** (e.g., by the drive member) relative to the body **111** and the ratchet collar **510** causes the ratchet collar **510** to move axially relative to the rotary collar **119** and the body **111**. The axial movement of the ratchet collar **510** may be brought about at least in part by the axial guide limiting rotation of the ratchet collar **510** relative to the body **111**. FIG. **3**A shows the ratchet collar **510** in a first axial position relative to the body **111**. Rotation of the rotary collar **119** for medicament delivery causes the ratchet collar **510** to move axially along the axis **144** in the distal direction, as shown in the progression of FIGS. **3**A to **3**K.
(83) The ratchet collar **510** comprises a pair of flexible arms **520***a*, **520***b* which extend in a proximal direction from a proximal surface of the main body of the ratchet collar **510**, adjacent to the inner surface of the body **111**, to each progressively engage the respective engagement elements **540** (e.g., respective engagement elements **540***a*, **540***b*, **540***c*, **540***d*). Each flexible arm **520***a*, **520***b* has a respective protrusion **530***a*, **530***b* that extends radially outwards from a free end of that flexible arm **520***a*, **520***b* such that the flexible arm **520***a*, **520***b* can engage the engagement elements **540** via the respective protrusion **530***a*, **530***b*. FIG. **3**A show the protrusions **530***a*, **530***b* arranged at a proximal end of each flexible arm **520***a*, **520***b*. However, it should be understood that in other examples the protrusions **530***a*, **530***b* may be located at a different portion of the flexible arms **520***a*, **520***b*, for example distal to the proximal end of the flexible arms **520***a*, **520***b*. The pair of flexible arms **520***a*, **520***b* may be located at symmetrical positions of the ratchet collar **510** about the axis **144**, as shown in FIG. **3**A, or at different locations around the axis **144**.
(84) In FIG. **5**A, only one flexible arm **520***a* and its corresponding protrusion **530***a* are shown, while the other flexible arm **520***b* and its corresponding protrusion **530***b* shown in FIG. **3**A are hidden in FIG. **5**A. However, it should be noted that in some alternative examples, the ratchet collar **510** comprises a single flexible arm **520***a* and corresponding protrusion **530***a* (i.e., flexible arm **520***b* is not present). In yet other examples, the ratchet collar **510** may comprise three flexible arms **520** and corresponding protrusions **530**, or a number of flexible arms **520** and corresponding

protrusions **530** that is greater than three.
(85) The plurality of engagement elements **540** are shown in FIGS. **3**A and **5**A to be arranged along an inner surface of the body **111**, however it should be understood that in other examples the engagement elements **540** are arranged along a different portion of the medicament delivery device **200** to the body **111**, but are fixed relative to the body **111**. The engagement elements **540** are configured to be engaged by the protrusion(s) **530** to limit axial movement of the ratchet collar **510** by the drive member.
(86) Each engagement element **540** may take the form of a projection such as a ridge. The engagement elements **540** are grouped into sets of engagement elements **540**, each set of engagement elements **540** forming a respective engagement track **545**. The number of engagement tracks **545** may correspond to the number of flexible arms **520** (e.g., each flexible arm **520** has a respective engagement track **545**). In FIG. **3**A, two flexible arms **520***a*, **520***b* are shown, each having a respective engagement track **545***a*, **545***b*, and each engagement track **545***a*, **545***b* comprising a plurality of respective engagement elements **540***a*-**540***d*. In alternative examples where the ratchet collar **510** comprises a single arm **520**, the ratchet mechanism **505** may comprise a single engagement track **545** comprising a plurality of engagement elements **540**.
(87) For each engagement track **545***a*, **545***b*, the engagement elements **540** of that engagement track **545***a*, **545***b* are aligned along the inner surface of the body **111**, along a respective axis that is substantially parallel to the axis **144**. As such, each engagement track **545***a*, **545***b* extends axially along the inner circumferential surface of the body **111**, parallel to the axis **144**. Where a plurality of engagement tracks **545***a*, **545***b* are present, the engagement tracks **545***a*, **545***b* are arranged circumferentially around the inner circumferential surface of the body **111**, with each engagement track **545***a*, **545***b* parallel to, but circumferentially separated from, its adjacent engagement track(s) **545***a*, **545***b*. FIG. **3**A shows two engagement tracks **545***a*, **545***b*, each separated by 180 degrees about the axis **144** such that they are symmetrical about the axis **144**. Each engagement track **545***a*, **545***b* is located adjacent its corresponding flexible arm **520***a*, **520***b*.
(88) In FIG. **5**A, only one of the engagement tracks **545***a* is shown, while the other engagement track **545***b* shown in FIG. **3**A is hidden in FIG. **5**A. However, it should be noted that in some alternative examples the ratchet mechanism **505** comprises a single engagement track **545** (e.g., where the ratchet collar **510** comprises a single flexible arm **520**). In yet other examples, the ratchet mechanism **505** may comprise three or more engagement tracks **545** spaced around the body **111** (e.g., where the ratchet collar **510** comprises three or more flexible arms **520**).
(89) It should be noted that FIG. **3**A shows the medicament delivery device **200** comprising four engagement elements **540***a*-**540***d* per engagement track **545***a*, **545***b*, whereas FIG. **5**A shows only three engagement elements **540***a*-*c*. The fourth engagement element **540***d* may be hidden in FIG. **5**A, or it may not be present.
(90) Each engagement track **545***a*, **545***b* may comprise the same number of engagement elements **540**, wherein the number of engagement elements **540** in each engagement track **545** may correspond to the number of discrete doses of the medicament **115** that may be dispensed by the medicament delivery device **200**, as explained later.
(91) In examples where the medicament delivery device **200** is configured to dispense at least two discrete doses of medicament **115**, each engagement track **545** may comprise at least two engagement elements **540***a*, **540***b*. In examples where the medicament delivery device **200** is configured to dispense at least three discrete doses of medicament **115**, each engagement track **545** may comprise at least three engagement elements **540***a*, **540***b*, **540***c*. In examples where the medicament delivery device **200** is configured to dispense at least n (e.g., n=1, 2, 3, . . .) discrete doses of medicament **115**, each engagement track **545** may comprise at least n engagement elements **540**.
(92) Adjacent engagement elements **540** are separated by a distance in the direction of the axis **144** that corresponds to a predetermined size of a respective dose of medicament **115** to be dispensed.

Each engagement element **540** of each engagement track **545** may be located at the same axial position with respect to the axis **144** as an engagement element **540** of the other engagement track(s) **545**. For example, FIG. **3**A shows a first engagement element **540***a* of the first engagement track **545***a* is located at the same axial position with respect to the axis **144** as a first engagement element **540***a* of the second engagement track **545***b* (i.e., they lie in the same plane normal to the axis **144**). Similarly, a second engagement element **540***b* of the first engagement track **545***a* is located at the same axial position with respect to the axis **144** as a second engagement element **540***b* of the second engagement track **545***b*, a third engagement element **540***c* of the first engagement track **545***a* is located at the same axial position with respect to the axis **144** as a third engagement element **540***c* of the second engagement track **545***b*, and a fourth engagement element **540***d* of the first engagement track **545***a* is located at the same axial position with respect to the axis **144** as a fourth engagement element **540***d* of the second engagement track **545***b*.

(93) The protrusion **530***a*, **530***b* of each flexible arm **520***a*, **520***b* of the ratchet collar **510** is configured to sequentially engage with each engagement element **540** in a corresponding engagement track **545***a*, **545***b* during a medicament delivery process, such that the medicament **115** can be delivered in the plurality of discrete, predefined doses, as described in more detail later.

(94) As shown in FIGS. **3**A and **5**A, the actuation member **404** comprises a button **410** arranged at a proximal end of the medicament delivery device **200** to extend proximal to the proximal end **130** of the body **111** and having a proximal actuation surface **412** configured to be pushed by a user.

(95) The actuation member **404** is configured to be actuated relative to the body **111**. The actuation member **404** is actuatable by a user between a first axial position and a second axial position relative to the body **111**. Each actuation of the actuation member **404** comprises a movement of the actuation member **404** between the first axial position and the second axial position.

(96) FIG. **3**A shows the actuation member **404** in the first axial position relative to the body **111**, while FIG. **3**C shows the actuation member **404** in the second axial position relative to the body **111**, the actuation member **404** having been moved distally from the first axial position to the second axial position by actuation (e.g., movement in the distal direction) of the actuation member **404** by a user. A user may apply a distal axial force to the actuation member **404** by directly pressing the proximal actuation surface **412** of the actuation member **404** with a thumb or finger to move the actuation member **404** distally between the first axial position and the second axial position. The button **410** is arranged to be pushed a first time by the user to provide a first actuation and pushed a second time by the (or a different) user to provide a second actuation (and pushed a third time by the user to provide a third actuation etc.).

(97) The actuation member **404** may be biased from its second axial position to its first axial position by an actuation member biasing member such as a spring **171**, however other forms of actuation member biasing member to a spring **171** may be envisaged.

(98) The actuation member **404** and the ratchet mechanism **505** are arranged such that actuation of the actuation member **404** (e.g., movement of the actuation member **404** from its first axial position to its second axial position) can be used move the ratchet mechanism **505** between configurations to dispense a dose of medicament **115**, as described later in relation to FIGS. **5**A-**5**G. For example, a first actuation of the actuation member **404** moves the ratchet mechanism **505** from the first configuration to the second configuration to cause a first dose of the medicament **115** to be dispensed, and a second actuation of the actuation member **404**, subsequent to the first actuation, moves the ratchet mechanism **505** from the second configuration to the third configuration to cause a second dose of the medicament **115** to be dispensed. Subsequent actuations of the actuation member **404** may be used to dispense subsequent discrete doses of medicament **115**.

(99) The actuation member **404** comprises a pair of elongate arms **420***a*, **420***b* that extend substantially in a distal direction from a distal end of the button **410**, substantially parallel to the axis **144** and within the body **111**. Each arm **420** extends adjacent the inner circumferential surface of the body **111**, substantially parallel to said surface. The two arms **420***a*, **420***b* are arranged

symmetrically either side of the axis **144**.
(100) Each arm **420***a*, **420***b* has a plurality of apertures **430** (e.g., apertures **430***a*, **430***b*, **430***c*, **430***d*), wherein the plurality of apertures **430** on each arm **420***a*, **420***b* are arranged along an axis that is substantially parallel to the axis **144**. Each arm **420** further comprises a plurality of guide surfaces **440** (e.g., guide surfaces **440***a*, **440***b*, **440***c*, **440***d*), arranged such that the apertures **430** and guide surfaces **440** alternate in an axial direction, with each pair of adjacent apertures **430** having a guide surface **440** between. Each of the apertures **430** extend in a radial direction through their respective arm **420**, from an inner surface of their respective arm **420** (nearest the axis **144**) to an outer surface of their respective arm **420** (furthest from the axis **144**). Each engagement element **540** is axially aligned with a corresponding aperture **440**.
(101) Operation of the ratchet mechanism **505** for dispensing the medicament **115** in a plurality of discrete doses shall now be described with particular reference to FIGS. **5**A-**5**G.
(102) FIG. **5**A shows the proximal end of the medicament delivery device **500** (which may be identical or similar to the medicament delivery device **200**) prior to medicament delivery.
(103) The medicament delivery device **500** may have been positioned at an injection site of a subject (who may be the user of the device **500**, or a different person/animal). The needle cover **113** may have been moved from its extended position to its retracted position as the medicament delivery device **500** was positioned at the injection site.
(104) FIG. **5**A shows the ratchet mechanism **505** in its first configuration. The actuation member **404** is at its first axial position relative to the body **111**, and may be biased into this position by the spring **171**. The rotary collar **119** is biased to rotate by the drive member, but is inhibited from rotation relative to the body **111** by the ratchet mechanism **505**. More specifically, the protrusion **530***a* of the flexible arm **520***a* of the ratchet collar **510** is engaged with the first engagement element **540***a* of the first engagement track **545***a* (e.g., by engagement between a distal-facing engaging surface **532***a* of the protrusion **530***a* and a proximal-facing engaging surface **542***a* of the first engagement element **540***a*), such that axial movement of the ratchet collar **510** in the distal direction is limited (e.g., prevented).
(105) Since the ratchet collar **510** is prevented from moving distally relative to the body **111**, the interface between the ratchet collar **510** and the rotary collar **119** limits (e.g., prevents) rotation of the rotary collar **119** by the drive member, which in turn limits (e.g., prevents) axial movement of the plunger **121** in the distal direction relative to the body **111** due to the interface between the rotary collar **119** and the plunger **121**. As such, the medicament delivery mechanism **180** does not operate to dispense the medicament while the ratchet collar **510** is engaged with the first engagement element **540***a*.
(106) FIG. **5**B shows the medicament delivery device **500** of FIG. **5**A after delivery of a first dose of the medicament **115** has been initiated, by a first actuation of the actuation member **404**. For example, a user may have applied a force to the proximal actuation surface **412** of the button **410** in a distal direction using a finger or thumb, moving the actuation member **404** distally from its first axial position shown in FIG. **5**A to its second axial position shown in FIG. **5**B.
(107) The distal movement of the actuation member **404** to its second axial position causes the arm **420** of the actuation member **404** to disengage the protrusion **530***a* from the first engagement element **540***a*. As shown from FIG. **5**A to FIG. **5**B, the arm **420***a* engages the protrusion **530***a* of the flexible arm **520***a* such that the flexible arm **520***a* is flexed radially inwards as the arm **420***a* moves distally. More specifically, a distal-facing surface **432***a* of the first aperture **430***a* of the arm **420***a* engages a proximally-facing ramped surface **534***a* of the protrusion **530***a* to urge the protrusion **530***a* and flexible arm **520***a* to flex radially inwards. As the flexible arm **520***a* is flexed radially inwards, the protrusion **530***a* is disengaged from the first engagement element **540***a* of the first engagement track **545***a*.
(108) Disengagement of the protrusion **530***a* from the first engagement element **540***a* allows the ratchet collar **510** to move axially with respect to the body **111**, for dispensing a first dose of the

medicament. Since axial movement of the ratchet collar **510** is no longer limited, the ratchet collar **510** releases the rotary collar **119** for rotation under the bias of the drive member, causing the ratchet collar **510** to move axially in a distal direction due to the interface between the ratchet collar **510** and rotary collar **119**. As the ratchet collar **510** moves distally, the protrusion **530***a* moves distally, passing over the first engagement element **540***a* of the first engagement track **545***a* and moving towards the second engagement element **540***b* of the first engagement track **545***a*. Rotation of the rotary collar **119** by the drive member simultaneously causes movement of the plunger **121** in the distal direction to dispense the first dose of medicament, due to the interface between the plunger **121** and the rotary collar **119**, with the ratchet collar **510** moving towards its position shown in FIG. **5**C.

(109) After actuating the actuation member **404** a first time to initiate the medicament delivery, the user may release the actuation member **404** such that it moves proximally from its second axial position back to its first axial position (e.g., under the biasing force of the spring **171**).

(110) If the user fails to release the actuation member **404** in sufficient time before the protrusion **530***a* has moved distally over the first engagement element **540***a*, the protrusion **530***a* and flexible arm **520***a* ay move radially outwards due to the resiliency of the flexible arm **520***a*, once the protrusion **530***a* is no longer engaged with the first engagement element **540***a*. In such circumstances, the protrusion **530***a* may be received within the first aperture **430***a* of the arm **430***a*, with the protrusion **530***a* moving distally through the first aperture **430***a* with distal movement of the ratchet collar **510** until the protrusion **530***a* engages a proximal-facing surface **434***a* of the first aperture **430***a*. The proximal-facing surface **434***a* of the first aperture **430***a* may be ramped such that protrusion **530***a* may continue to move distally over the ramped proximal-facing surface **434***a* of the first aperture **430***a*. Engagement between the protrusion **530***a* and the ramped proximal-facing surface **434***a* causes the protrusion **530***a* and flexible arm **520***a* to be moved radially inwards as the ratchet collar **510** continues to move distally. The protrusion **530***a* will then reach the first guide surface **440***a* of the arm **420** and continue moving distally across the first guide surface **440***a*, towards the second engagement element **540***b*.

(111) If the actuation member **404** is moved from its second axial position back to its first axial position before the protrusion **530***a* reaches the second engagement element **540***b*, proximal movement of the actuation member **404** will bring the second aperture **430***b* of the arm **420***a* into alignment with the protrusion **530***a* such that the protrusion **530***a* is no longer radially supported by the first guide surface **440***a*. As such, the protrusion **530***a* moves radially outwards due to the resiliency of the flexible arm **520***a*, into the second aperture **430***b*. The protrusion **530***a* continues moving distally thought the second aperture **430***b* until it engages the second engagement element **540***b* of the first engagement track **545***a* (e.g., the distal-facing engaging surface **532***a* of the protrusion **530***a* engages the proximal-facing engaging surface **542***b* of the second engagement element **540***b*), at which point further axial movement of the ratchet collar **510** in the distal direction is limited (e.g., prevented) by the engagement between the protrusion **530***a* and the second engagement element **540***b*, as shown in FIG. **5**C. FIG. **5**C shows the ratchet mechanism **505** in its second configuration.

(112) Note that if the actuation member **404** was instead moved from its second position to its first position before the protrusion **530***a* had moved distally over the entire first engagement element **540***a*, then the protrusion **530***a* may avoid being moved radially outwards into the first aperture **430***a* once it is no longer radially supported by the first engagement element **540***a*. Instead, the protrusion **530***a* may move straight onto the first guide surface **440***a* after it has moved off the first engagement element **540***a* (or briefly onto the ramped proximal-facing surface **434***a* before moving onto the first guide surface **440***a*), before traversing the first guide surface **440***a* and then second aperture **430***b* as previously described, until engaging the second engagement element **540***b* as shown in FIG. **5**C.

(113) The axial distance between the first and second engagement elements **540***a*, **540***b*, and

therefore the distance travelled by the protrusion **530***a* between the first and second engagement elements **540***a*, **540***b*, corresponds to the size (i.e., amount) of the discrete, predetermined first dose of medicament **115** expelled by the medicament delivery mechanism **180**. The distance between the first and second engagement elements **540***a*, **540***b* may therefore be tailored for different types of medicament **115** and/or different dose regimens etc.

(114) After the first dose of medicament **115** has been dispensed, the user may wish to remove the medicament delivery device **500** from the injection site of the subject. For example, the dose regimen of the medicament **115** may require administration of the medicament **115** to a subject in a plurality of doses, each separated by a sufficient period of time (e.g. three doses to be administered, each dose separated by a week). Additionally or alternatively, the user may wish to use the medicament delivery device **500** to deliver one or more subsequent doses of medicament **115** to a different injection site of the subject (e.g. three doses are to be administered to the subject, each at a different injection sites of the subject). In other examples, the user may wish to use the same medicament delivery device **500** to administer one or more subsequent doses of medicament **115** to a different subject (or subjects) to the subject that received the first dose of medicament **115** (e.g. three doses are to be administered, each dose administered to a different subject, such as a different person). It should be noted that dividing the medicament **115** into three doses for separate administration has been provided merely by way of example, and that in other examples the medicament **115** may be delivered as two doses, or four or more doses. It should also be noted that in some examples, the user may not remove the medicament delivery device **500** from the injection site between the delivery of each dose. Rather, the needle **117** may remain in the injection site after delivery of the first dose and the user may cause a one or more subsequent doses to be delivered to the injection site in succession, for example each dose separated by a dwell time.

(115) To dispense a second dose of medicament **115**, the user actuates the actuation member **404** from its first axial position to its second axial position a second time, for example in a similar manner as previously described in relation to FIGS. **5**A and **5**B. FIG. **5**D shows the medicament delivery device **500** of FIG. **5**C after the actuation member **404** has been moved from its first axial position to its second axial position with a second actuation action. In a similar manner as previously described in relation to FIG. **5**B, the axial movement of the actuation member **404** has disengaged the protrusion **530***a*, however this time the protrusion **530***a* is disengaged from a proximally-facing engaging surface **542***b* of the second engagement element **540***b* of the first engagement track **545***a*, rather than from the proximally-facing engaging surface **542***a* of the first engagement element **540***a*. Furthermore, the protrusion **530***a* has been disengaged from the second engagement element **540***b* by engagement between a distal-facing surface **432***b* of the second aperture **430***b* and the proximally-facing ramped surface of the protrusion **530***a*, rather than engagement between the distal-facing surface **432***a* of the first aperture **430***a* and the proximally-facing ramped surface of the protrusion **530***a*.

(116) Disengagement of the protrusion **530***a* from the second engagement element **540***b* causes the ratchet collar **510** and the plunger **121** to move distally relative to the body **111** and rotary collar **119**, due to rotation of the rotary collar **119** by the drive member, as described previously.

(117) As the ratchet collar **510** moves distally, the protrusion **530***a* moves distally, passing over the second engagement element **540***b* of the first engagement track **545***a* and moving towards the third engagement element **540***c* of the first engagement track **545***a*. Rotation of the rotary collar **119** by the drive member simultaneously causes movement of the plunger **121** in the distal direction to dispense the second dose of medicament, due to the interface between the plunger **121** and the rotary collar **119**.

(118) After actuating the actuation member **404** to initiate the delivery of the second dose of medicament **115**, the user may release the actuation member **404** such that it moves proximally from its second axial position back to its first axial position (e.g., under the biasing force of the spring **171**).

(119) If the user fails to release the actuation member **404** in sufficient time before the protrusion **530***a* has moved distally over the second engagement element **540***b*, the protrusion **530***a* and flexible arm **520***a* a may move radially outwards due to the resiliency of the flexible arm **520***a*, once the protrusion **530***a* is no longer engaged with the second engagement element **540***b*. In such circumstances, the protrusion **530***a* may be received within the second aperture **430***b* of the arm **430***a*, with the protrusion **530***a* moving distally through the second aperture **430***b* with distal movement of the ratchet collar **510** until the protrusion **530***a* engages a proximal-facing surface **434***b* of the second aperture **430***b*. The proximal-facing surface **434***b* of the second aperture **430***b* may be ramped such that protrusion **530***a* may continue to move distally over the ramped proximal-facing surface **434***b* of the second aperture **430***b*. Engagement between the protrusion **530***a* and the ramped proximal-facing surface **434***b* causes the protrusion **530***a* and flexible arm **520***a* to be moved radially inwards as the ratchet collar **510** continues to move distally. The protrusion **530***a* will then reach the second guide surface **440***b* of the arm **420***a* and continue moving distally across the second guide surface **440***b*, towards the third engagement element **540***c*.
(120) If the actuation member **404** is moved from its second axial position back to its first axial position before the protrusion **530***a* reaches the third engagement element **540***c*, proximal movement of the actuation member **404** will bring the third aperture **430***c* of the arm **420***a* into alignment with the protrusion **530***a* such that the protrusion **530***a* is no longer radially supported by the second guide surface **440***b*. As such, the protrusion **530***a* moves radially outwards due to the resiliency of the flexible arm **520***a*, into the third aperture **430***c*. The protrusion **530***a* continues moving distally thought the third aperture **430***c* until it engages the third engagement element **540***c* of the first engagement track **545***a* (e.g., the distal-facing engaging surface **532***a* of the protrusion **530***a* engages the proximal-facing engaging surface **542***c* of the third engagement element **540***c*), at which point further axial movement of the ratchet collar **510** in the distal direction is limited (e.g., prevented) by the engagement between the protrusion **530***a* and the third engagement element **540***c*, as shown in FIG. **5**E. FIG. **5**E shows the ratchet mechanism **505** in its third configuration.
(121) Note that if the actuation member **404** was instead moved from its second position to its first position before the protrusion **530***a* had moved distally over the entire second engagement element **540***b*, then the protrusion **530***a* may avoid being moved radially outwards into the second aperture **430***b* once it is no longer radially supported by the second engagement element **540***b*. Instead, the protrusion **530***a* may move straight onto the second guide surface **440***b* after it has moved off the second engagement element **540***b* (or briefly onto the ramped proximal-facing surface **434***b* before moving onto the second guide surface **440***b*), before traversing the second guide surface **440***b* and then third aperture **430***c* as previously described, until the engaging the third engagement element **540***c* as shown in FIG. **5**E.
(122) The axial distance between the second and third engagement elements **540***b*, **540***c*, and therefore the distance travelled by the protrusion **530***a* between the second and third engagement elements **540***b*, **540***c*, corresponds to the size (i.e., amount) of the discrete, predetermined second dose of medicament **115** expelled by the medicament delivery mechanism **180**. The distance between the second and third engagement elements **540***b*, **540***c* may therefore be tailored for different types of medicament **115** and/or different dose regimens etc.
(123) To dispense a third dose of medicament **115**, the user once again actuates the actuation member **404** from its first axial position to its second axial position, for example in a similar manner as previously described in relation to FIGS. **5**A and **5**B. The user may or may not have removed and repositioned the medicament delivery device **500** prior to actuation of the actuation member **404** to dispense the third dose of medicament **115**.
(124) FIG. **5**F shows the medicament delivery device **500** of FIG. **5**E after the actuation member **404** has been moved from its first axial position to its second axial position with a third actuation. In a similar manner as previously described in relation to FIG. **5**B, the axial movement of the actuation member **404** has disengaged the protrusion **530***a*, however this time the protrusion is

disengaged from a proximally-facing engaging surface **542***c* of the third engagement element **540***c* of the first engagement track **545***a*, rather than from the proximally-facing engaging surface **542***a* of the first engagement element **540***a*. Furthermore, the protrusion **530***a* has been disengaged from the third engagement element **540***c* by engagement between a distal-facing surface **432***c* of the third aperture **430***c* and the proximally-facing ramped surface of the protrusion **530***a*, rather than engagement between the distal-facing surface **432***a* of the first aperture **430***a* and the proximally-facing ramped surface of the protrusion **530***a*.

(125) Disengagement of the protrusion **530***a* from the third engagement element **540***c* causes the ratchet collar **510** and the plunger **121** to move distally relative to the body and rotary collar **119**, due to rotation of the rotary collar **119** by the drive member, as described previously.

(126) As the ratchet collar **510** moves distally, the protrusion **530***a* moves distally, passing over the third engagement element **540***c* of the first engagement track **545***a*. Unlike FIGS. **3**A-**3**K, FIGS. **5**A-**5**G do not show a fourth engagement element **540***d* of the first engagement track **545***a*, nevertheless the protrusion **530***a* would move towards such a fourth engagement element **540***d* of the first engagement track **545***a* if present.

(127) Rotation of the rotary collar **119** by the drive member simultaneously causes movement of the plunger **121** in the distal direction to dispense the third dose of medicament, due to the interface between the plunger **121** and the rotary collar **119**.

(128) After actuating the actuation member **404** to initiate the delivery of the third dose of medicament **115**, the user may release the actuation member **404** such that it moves proximally from its second axial position back to its first axial position (e.g., under the biasing force of the spring **171**).

(129) If the user fails to release the actuation member **404** in sufficient time before the protrusion **530***a* has moved distally over the third engagement element **540***c*, the protrusion **530***a* and flexible arm **520***a* a may move radially outwards due to the resiliency of the flexible arm **520***a*, once the protrusion **530***a* is no longer engaged with the third engagement element **540***c*. In such circumstances, the protrusion **530***a* may be received within the third aperture **430***c* of the arm **430***a*, with the protrusion **530***a* moving distally through the third aperture **430***c* with distal movement of the ratchet collar **510** until the protrusion **530***a* engages a proximal-facing surface **434***c* of the third aperture **430***c*. The proximal-facing surface **434***c* of the third aperture **430***c* may be ramped such that protrusion **530***a* may continue to move distally over the ramped proximal-facing surface **434***c* of the third aperture **430***c*. Engagement between the protrusion **530***a* and the ramped proximal-facing surface **434***c* causes the protrusion **530***a* and flexible arm **520***a* to be moved radially inwards as the ratchet collar **510** continues to move distally. The protrusion **530***a* will then reach the third guide surface **440***c* of the arm **420***a* and continue moving distally across the third guide surface **440***c*, towards, if present, the next engagement element **540** (e.g., towards the fourth engagement element **540***d* of medicament delivery device **200** of FIGS. **3**A-**3**K).

(130) If the actuation member **404** was instead moved from its second position to its first position before the protrusion **530***a* had moved distally over the entire third engagement element **540***c*, then the protrusion **530***a* may avoid being moved radially outwards into the third aperture **430***c* once it is no longer radially supported by the third engagement element **540***c*. Instead, the protrusion **530***a* may move straight onto the third guide surface **440***c* after it has moved off the third engagement element **540***c* (or briefly onto the ramped proximal-facing surface **434***c* before moving onto the third guide surface **440***c*), before traversing the third guide surface **440***b* (and then third aperture **430***c*, if present, until engaging the fourth engagement element **540***d*, if present).

(131) Unlike the medicament delivery device **200** as shown in FIGS. **3**A-**3**K, the medicament delivery device **500** device as shown in FIGS. **5**A-**5**G does not have a fourth aperture **430***d* of the first arm **420***a*, nor is a fourth engagement element **540***d* present in the first engagement track **545***a*. As such, after the protrusion **530***a* has moved distally across the third guide surface **440***c* to the distal end of the third guide surface **440***c*, the protrusion **530***a* and flexible arm **520***a* move radially

outwards, towards the inner surface of the body **111**, due to the protrusion **530***a* no longer being radially supported by the third guide surface **440***c*. The ratchet collar **510** will continue moving distally until it is limited from moving further. For example, FIG. **5**G shows a distally-facing surface of the ratchet collar **510** engaging a proximally-facing surface of the rotary collar **119** to limit further distal movement of the ratchet collar **510**. In other examples, further distal movement of the ratchet collar **510** may limited by a different mechanism, for example the drive member may no longer provide a biasing force to rotate the rotary collar **119** (e.g., because the spring has depleted its stored elastic energy), or the plunger **121** may engage a stop feature that limits further distal movement of the plunger **121**.

(132) It should be noted that in some alternative examples, no guide surface **440** is provided distal to the final engagement element **540**. For example, and with reference to FIG. **5**G, in some examples the third guide surface **440** is not present (i.e., there is no guide surface **440** distal to the third engagement element **540***c*). As such, the protrusion **530***a* may not contact the arm **420***a* after distally traversing the third engagement element **540***c*.

(133) FIG. **5**G shows the medicament delivery device **500** of FIG. **5**F after delivery of the third dose of medicament is complete, with the ratchet mechanism **505** in a fourth configuration.

(134) Returning to FIG. **3**A, the actuation member latch **450** is now described.

(135) The actuation member latch **450** is configured to limit distal axial movement of the actuation member **404** from its first axial position to its second axial position. The actuation member latch **450** is movable between a locked configuration, in which distal axial movement of the actuation member **404** from its first axial position to its second axial position is limited (e.g., prevented) by the actuation member latch **450**, and an unlocked configuration, in which distal axial movement of the actuation member **404** from its first axial position to its second axial position is allowed (not limited) by the actuation member latch **450**. FIG. **3**A shows the actuation member latch **450** in the locked configuration, while FIG. **3**C shows the actuation member latch **450** in the unlocked configuration.

(136) The actuation member latch **450** is configured to be moved from the locked configuration to the unlocked configuration by the needle cover **113**, as described in more detail in relation to FIGS. **4**A-**4**C.

(137) FIGS. **4**A-**4**C show a schematic cross-section of part of a medicament delivery device **400**, which may be similar or identical to the medicament delivery device **200**, showing various operational states of the actuation member latch **450** in greater detail. FIGS. **4**A-**4**C show only a proximal portion of the medicament delivery device **400**, with only the components on one side of the axis **144** shown. Various features of the medicament delivery device **200** that may be present in the medicament delivery device **400** are hidden in FIGS. **4**A-**4**C.

(138) FIG. **4**A shows portions of the actuation member **404**, actuation member latch **450**, needle cover **113** and body **111** of the medicament delivery device **200** when in its first state previously described in relation to FIG. **3**A. FIG. **4**A shows the actuation member latch **450** in its locked configuration, in which distal axial movement of the actuation member **404** from its first axial position to its second axial position is limited (e.g., prevented) by the actuation member latch **450**. The actuation member latch **450** comprises a flexible extension **452** coupled to the arm **420** of the actuation member **404**, for example at a distal end of the arm **420**. A projection **454** extends from a free end of the flexible extension **452** to engage a recess **456** in a latch element **458**. FIG. **4**A shows the projection **454** extending radially inwards to engage the recess **456**.

(139) FIG. **4**A shows the needle cover **113** in its extended position. When in the extended position, the needle cover **113** limits (i.e., prevents) movement of the actuation member latch **450** from its locked configuration to its unlocked configuration. As shown in FIG. **4**A, an inner surface of the needle cover **113** is located adjacent the flexible extension **452** such that radial movement of the flexible extension **452** and the projection **454** to disengage the projection **454** from the recess **456** is limited. As such, the needle cover **113** holds the actuation member latch **450** in its locked

configuration when the needle cover **113** is in its extended position and, as a consequence, distal movement of the actuation member **404** from its first axial position shown in FIG. **4**A to its second axial position shown in FIG. **4**C is limited (e.g., prevented).
(140) FIG. **4**B shows the portions of the actuation member **404**, actuation member latch **450**, needle cover **113** and body **111** of the FIG. **4**A, once the actuation member latch **450** has been moved from its locked configuration to its unlocked configuration by the needle cover **113**.
(141) FIG. **4**B shows the needle cover **113** of FIG. **4**A after it has been moved proximally with respect to the body **111** from its extended position to its retracted position, for example in response to a user pressing the needle cover **113** against an injection site. As the needle cover **113** has moved proximally, a recess **460** in the needle cover **113** has been brought into radial alignment with the actuation member latch **450** to allow the actuation member latch **450** to be moved from its locked configuration to its unlocked configuration. More specifically, in this example, the recess **460** has been moved into radial alignment with at least a portion of the flexible extension **452** such that the flexible extension **452** is no longer prevented from moving radially outwards by an inner surface of the needle cover **113**. Rather, at least a portion of the flexible extension **452** may now be received in the recess **460** of the needle cover **113** when the flexible extension **452** moves radially outwards. The movement of the needle cover **113** has therefore moved actuation member latch **450** from the locked configuration to the unlocked configuration. The recess **460** may be located on the needle cover **113** such that it aligns with the actuation member latch **450** once the needle **117** has reached a desired penetration depth in an injection site.
(142) It can be seen in FIG. **4**B that the projection **454** still remains engaged in the recess **456** of the latch element **458**. However, distal axial movement of the actuation member **404** from its first axial position to its second axial position is no longer limited (e.g., prevented) by the actuation member latch **450**, since distal axial movement of the actuation member **404** from its first axial position (shown in FIG. **4**B) to its second axial position (shown in FIG. **4**C) will cause the projection **454** to be disengaged from the recess **460**, as shown in FIG. **4**C. That is, engagement between a distal-facing surface **464** of the projection **454** and a proximal-facing surface **462** of the recess **456** of the latch element **458** during distal movement of the actuation member **404** urges the flexible extension **454** to move radially outwards and into the recess **460** of the needle cover **113**, bringing the projection **454** out of engagement with the recess **456** of the latch element **458**. In some examples, either or both of the proximal-facing surface **462** and the distal-facing surface **464** may be ramped to assist with urging the projection **454** to disengaged from the recess **456**.
(143) As the actuation member **404** moves in a proximal direction relative to the body **111**, back from its second axial position shown in FIG. **4**C to its first axial position shown in FIG. **4**B, the flexible extension **452** moves radially inwards to bring the projection **454** back into engagement with the recess **456** of the latch element **458**. This may be due to the flexible extension **452** being resiliently biased to move radially inwards, for example due to at least a portion of the flexible extension being formed from a resilient material.
(144) As the needle cover **113** moves back from its retracted position shown in FIG. **4**B to its extended position shown in FIG. **4**A, for example due to a user removing the needle cover **113** from an injection site, the needle cover **113** may assist with urging the flexible extension **452** radially inwards to engage the projection **454** with the recess **456**, for example due to engagement between a proximal-facing surface **466** of the recess **456** and the flexible extension **452**. The actuation member latch **450** is now back in its locked configuration.
(145) Returning to FIG. **3**A, the medicament delivery device **200** further has a needle cover guide **143**, which may be arranged at least partially within the body **111**. The needle cover guide **143** is substantially cylindrical and is rotatable relative to the body **111**, for example about the axis **144**, but is axially fixed relative to the body **111**. FIG. **3**A shows the needle cover guide **143** arranged within the distal end **131** of the body **11** of the medicament delivery device **200**, however it should be understood that in other examples the needle cover guide **143** may be located at a different

location of the medicament delivery device **200**, for example proximal to the distal end **131** of the medicament delivery device **200**. The needle cover guide **143** comprises a track **128** arranged circumferentially around the needle cover guide **143**. In some examples a separate track **128** is provided for each arm **126** (if more than one arm **126***a*, **126***b* is present), or a single track **128** may be used for a plurality of arms **126***a*, **126***b*.

(146) As shown in FIG. **3**A, the needle cover **113** of the medicament delivery device **200** comprises a pair of guide extensions **610***a*, **610***b* arranged to engage the track **128**. The arm-like guide extensions **610***a*, **610***b* extend radially outwards from the remainder of the needle cover **113**, such that free ends of the guide extensions **610***a*, **610***b* extend within the needle cover guide **143**. FIG. **3**A shows the guide extensions **610***a*, **610***b* extending in a proximal direction from the remainder of the needle cover **113**, at a slight acute angle to the axis **144**, however it should be understood that the guide extensions **610***a*, **610***b* may extend in a different manner to engage the needle cover guide **143**. For example, in some examples the guide extensions **610***a*, **610***b* may extend substantially radially outwards from the remainder of the needle cover **113**, substantially perpendicular to the axis **144**.

(147) Each guide extension **610***a*, **610***b* has a respective guide protrusion **620***a*, **620***b* configured to engage the track **128**, such that each guide extension **610***a*, **610***b* engages the track **128** via its respective guide protrusion **620***a*, **620***b*. FIG. **3**A shows the guide protrusions **620***a*, **620***b* at the free (e.g., proximal) end of each guide extension **610***a*, **610***b*, although in other embodiments the guide protrusions **620***a*, **620***b* may be located distally from the free end of the guide extensions **610***a*, **610***b*. The guide extensions **610***a*, **610***b* and/or guide protrusions **620***a*, **620***b* may be flexible, as discussed later.

(148) The track **128** is configured to be engaged by the one or more guide protrusions **620***a*, **620***b* of the needle cover **113** such that an axial movement of the needle cover **113** from the extended position to the retracted position causes a rotation of the needle cover guide **143** relative to the needle cover **113**.

(149) FIGS. **6**A-**6**F show the various operations of the needle cover guide **143** and the needle cover **113** of the medicament delivery device **200** in more detail.

(150) FIG. **6**A shows a perspective view of the needle cover guide **143** and the needle cover **113** of the medicament delivery device **200** when in its first state shown in FIG. **3**A. Only a distal portion of the needle cover **113** including the guide extensions **610** and respective guide protrusions **620** is shown. Various other features of the medicament delivery device **200** may be hidden for clarity.

(151) FIG. **6**A shows the needle cover guide **143** comprising a tool engagement feature **670** arranged at a distal end of the needle cover guide **143**, the purpose of which shall be explained later.

(152) The track **128** is configured to limit a proximal movement of the needle cover **113** relative to the body **111**, after the needle cover **113** has moved from the retracted position back to the extended position. That is, the or each guide extension **610** is configured to engage the track **128** via its respective guide protrusion **620** such that a proximal movement of the needle cover **113** is limited after the needle cover **113** has moved from the retracted position to the extended position.

(153) FIG. **6**A shows the track **128** comprising a plurality of track portions **630***a*-**630***f* arranged circumferentially around the needle cover guide **143**. FIG. **6**A shows the track **128** comprising six track portions **630***a*-**630***f*, however it should be understood that this is not meant to be limiting and that in other examples fewer than six (i.e., from one to five) or greater than six track portions **630***a*-**630***f* may be present.

(154) Each track portion **630***a*-**630***f* generally comprises a respective first region **641**, second region **642** and third region **643**. However, in some examples the first track portion **630***a* does not comprise a third region **641**. Additionally or alternatively, in some examples, at least one of the track portions **630***b*-**630***f* does not comprise a first region **641** and/or second region **642**.

(155) FIG. **6**A shows each first region **641**, second region **642** and third region **643** of the track

portions **630***a*-**630***f* formed as apertures/cut-outs in the needle cover guide **143**. However, it should be understood that this is not meant to be limiting and that in other examples, one or more (e.g., all) of the first region **641**, second region **642** and third region **643** of the track portions **630***a*-**630***f* may be in the form of grooves in the internal surface of the needle cover guide **143** (or external surface of the needle cover guide **143**, if the guide extensions **610** are extend radially outside of the needle cover guide **143**).

(156) FIG. **6**A shows each guide extension **610***a*, **610***b* extending in a substantially proximal direction, within the needle cover guide **143**. The guide protrusions **620***a*, **620***b* extend radially outwards from their respective guide extension **610***a*, **610***b* such that they are each retained within a respective track portions **630***a*-**630***f* of the track **128**. In this example, one guide protrusion **620***a* engages a first of the track portions **630***a* while the other guide protrusion **620***b* engages a fourth of the track portions **630***d*. Each guide protrusion **620***a*, **620***b* is currently at a respective first position **651** within the first region **641** of its respective track portion **630***a*, **630***d*.

(157) Returning to FIG. **3**A, an example operation of the medicament delivery **200** to dispense a plurality of discrete doses of medicament shall now be described.

(158) In the first state of the medicament delivery device **200** shown in FIG. **3**A, movement of the actuation member **404** from its first axial position to its second axial position is initially limited (e.g., prevented) due to the actuation member latch **450** being in its locked configuration, (e.g., as previously described in relation to FIG. **4**A).

(159) A user may begin a medicament delivery process to dispense a first dose of the medicament **115** by placing a distal end **120** of the needle cover **113** against an injection site of a subject. The subject may be a human or an animal. In some examples the user is also the subject (i.e., in the case of self-injection), however in other examples the user and subject are different people (e.g., the user is a healthcare professional and the subject is a patient).

(160) After placing the distal end **120** of the needle cover **113** against the injection site, the body **111** is moved towards the injection site, causing relative movement between the needle cover **113** and the body **111** as the needle cover **113** translates in the proximal direction from its extended position to its retracted position. As the needle cover **113** is moved distally, the needle cover **113** moves the actuation member latch **450** from its locked configuration to its unlocked configuration (e.g., as previously described in relation to FIGS. **4**A and **4**B), unlocking the actuation member **404** such that it may now be actuated.

(161) FIG. **3**B shows the medicament delivery device **200** of FIG. **3**A in a second state, wherein the needle cover **113** has been moved to its retracted position against the biasing force of the needle cover biasing member **118** and the actuation member latch **450** has been moved to its unlocked configuration (e.g., e.g., as previously described in relation to FIGS. **4**A and **4**B). As the needle cover **113** has moved proximally, the distal end **140** of the needle **117** has become progressively uncovered, allowing it to penetrate the injection site. Medicament delivery has not yet been initiated, due to the ratchet mechanism **505** still limiting movement of the medicament delivery mechanism **180** (e.g., as previously described in relation to FIG. **5**A).

(162) Proximal movement of the needle cover **113** has caused rotation of the needle cover guide **143** due to interaction between the guide arms **610** and the track **128**, as now explained in relation to FIG. **6**B.

(163) FIG. **6**B shows the configuration of the needle cover guide **143** and needle cover **113** once the medicament delivery device **200** has moved from its first state shown in FIG. **3**A to its second state shown in FIG. **3**B.

(164) Proximal movement of the needle cover **113** relative to the body **111** and needle cover guide **143** (as indicated by arrow **682**) has rotated the needle cover guide **143** (as indicated by arrow **684**) due to engagement between the guide protrusions **620** and their respective track portions **630***a*, **630***d*. Proximal movement of the needle cover **113** relative to the body **111** has moved the guide protrusions **620***a*, **620***b* proximally relative to the needle cover guide **143** such that the guide

protrusions **620***a*, **620***b* traverse the first region **641** of their respective track portions **630***a*, **630***d*, from their respective first positions **651** in the respective first regions **641** to respective second positions **652** in their respective second regions **642**.
(165) The first regions **641** each extend circumferentially and axially around the needle cover guide **143** (e.g., helically), with each first region **641** extending at an angle to the axis **144**. The second positions **652** are each located proximal to the first positions **651**, and spaced circumferentially from the first positions **651** around the needle cover guide **143**. The first regions **641** are shaped such that engagement between the guide protrusions **620***a*, **620***b* and the respective first regions **641** as the guide protrusions **620***a*, **620***b* traverse the respective first regions **641** converts proximal axial movement of the needle cover **113** into rotation of the needle cover guide **143** (e.g. by engagement between each guide protrusion **620***a*, **620***b* and a respective angled proximal wall **680** of the respective first region **541**). Proximal movement of guide protrusions **620***a*, **620***b* beyond the second positions **652** may be limited by engagement between the guide protrusions **620***a*, **620***b* and respective distal-facing surfaces **660** of the second regions **642**.
(166) Returning to FIG. **3**B, the user may now initiate delivery of the first dose of medicament **115** by actuating the actuation member **404**, for example as previously described in relation to FIG. **5**B. The user may actuate the actuation member **404** by pushing the proximal actuation surface **412** of the button **410** in the distal direction, causing the actuation member **404** to move distally from its first axial position (shown in FIG. **3**B) to its second axial positions (shown in FIG. **3**C), against the biasing force provided by the spring **171**.
(167) FIG. **3**C shows the medicament delivery device **200** of FIG. **3**B in a third state, in which medicament delivery has been initiated to dispense a first dose of medicament, for example as previously described in relation to FIG. **5**B. Movement of the actuation member **404** from its first axial position to its second axial position has caused the projection **454** of the actuation member latch **450** to disengage the recess **456** of the latch element **458** (e.g., as previously described in relation to FIG. **4**C).
(168) FIG. **3**D shows the medicament delivery device **200** of FIG. **3**C in a fourth state, after the user has released the actuation member **404**, allowing the actuation member **404** to move from its second axial position back to its first axial position due to the biasing force exerted by the spring **171**. A first dose of the medicament **115** has been dispensed by the medicament delivery mechanism **180**, via distal movement of the plunger **121** and piston **123** (e.g., as previously described in relation to FIGS. **5**B and **5**C). The ratchet mechanism **505** is in its second configuration.
(169) The actuation member latch **450** remains in its unlocked state while the needle cover **113** remains in its retracted state. Nevertheless, the projection **454** of the actuation member latch **450** may have re-engaged the recess **456** of the latch element **458** during the movement of the actuation member **404** (e.g., as previously described in relation to FIGS. **4**B and **4**C).
(170) FIG. **3**E shows the medicament delivery device **200** of FIG. **3**D in a fifth state, after the user has removed the medicament delivery device **200** from the injection site. As the body **111** of the medicament delivery device **200** has been moved away from the injection site, the needle cover **113** has moved distally from its retracted position shown in FIG. **3**D to its extended position shown in FIG. **3**E under the biasing force of the needle cover biasing member **118**, and in doing so has covered the needle **117** to protect the user and/or subject from an accidental needle-stick event.
(171) As the needle cover **113** has moved back to its extended position, the recess **460** of the needle cover **113** has moved out of radial alignment with the actuation member latch **450** such that the actuation member latch **450** has been moved from its unlocked position to its locked position (e.g., as previously described in relation to FIGS. **4**A-**4**C), limiting actuation of the actuation member **404**.
(172) As the needle cover **113** moves back from its retracted position shown in FIG. **3**D to its extended position shown in FIG. **3**E, the needle cover **113** is locked by the needle cover guide **143**

to limit subsequent proximal movement of the needle cover **113** from the extended position to the retracted position, as now described in relation to FIG. **6**C.

(173) As shown in FIG. **6**C, each second region **642** of each track portion **630** extends axially across the needle cover guide **143**, to allow the guide protrusion **620** to move distally from the second position **652** as the needle cover **113** moves from its retracted position to its extended position.

(174) For each track portion **630** arranged around the needle cover guide **143**, the third region **643** of that adjacent track portion **630** may be located distal to the second region **642** of the previous track portion **630** (i.e., the previous, adjacent track portion **630** arranged around the circumference of the needle cover guide **143**). For example, FIG. **6**C shows the third region **643** of the second track portion **630***b* located distal to the second region **642** of the first track portion **630***a*.

(175) The arrangement of the track portions **630** is such that distal movement of the needle cover **113** from its retracted position to its extended position causes the guide protrusions **620** to travel distally through a respective second region **642** of a respective track portion **630** into a respective third region **643** of the next track portion **630**, from their respective second position **652** in their respective second region **642** to a respective third position **653** in their respective third region **643**, wherein the third positions **653** are each distal to the second positions **652**, but axially aligned.

(176) For example, and as shown in FIG. **6**C, distal movement of the needle cover **113** from its retracted position shown in FIG. **6**B to its extended position shown in FIG. **6**C causes the guide protrusion **620***a* in the first track portion **630***a* to travel distally through a the second region **642** of the first track portion **630***a* into a third region **643** of the second track portion **630***b*, from its second position **652** in the second region **642** of the first track portion **630***a* to a third position **653** in the third region **643** of the second track portion **630***b*.

(177) The second regions **642** and third regions **643** are arranged such that the needle cover guide **143** is not substantially rotated relative to the needle cover **113** by the distal movement of the needle cover **113** relative to the needle cover guide **143**, as shown in FIG. **6**C.

(178) FIG. **6**C shows a locking element **690** arranged between the first track portion **630***a* and the second track portion **630***b*, between the second region **642** of the first track portion **630***a* and the third region **643** of the second track portion **630***b*.

(179) The locking element **690** is arranged to lock the needle cover **113** in its extended position after the needle cover **113** has moved from its retracted position to its extended position. That is, the locking element **690** is arranged such that an axial movement of the needle cover **113** from the retracted position to the extended position (subsequent to the rotation of the needle cover guide **143** previously described in relation to FIG. **6**B) engages the guide protrusion **620** with the locking element **690**, to limit (e.g., prevent) a further axial movement of the needle cover **113** from the extended position to the retracted position. The guide protrusion **620***a* moves over the locking element **690** as the guide protrusion **620***a* travels from the second region **642** of the first track portion **630***a* to the third region **643** of the second track portion **630***b*. Once the guide protrusion **620***a* reaches its third position **653** in the third region **643** of the second track portion **630***b*, the guide protrusion **620***a* becomes engaged with the locking element **690** to limit proximal movement of the needle cover **113** relative to the needle cover guide **143**.

(180) For example, the locking element **690** may comprise a proximally-facing ramped surface **692** and a distally-facing locking surface **694**, the distally-facing locking surface **694** located distal to the ramped surface **692**. As the guide protrusion **620***a* moves distally from the second region **642** of the first track portion **630***a* to the third region **643** of the second track portion **630***b*, it engages and traverses the proximally-facing ramped surface **692**, which causes the respective guide extension **610***a* (on which the guide protrusion **620***a* is located) to flex radially inwards, moving the guide protrusion **620***a* radially inwards. As the guide protrusion **620***a* continues to move distally and passes the distal end of the ramped surface **692**, the guide protrusion **620***a* is no longer radially supported by the ramped surface **692** and so is moved radially outwards as the guide extension

610*a* flexes radially outwards (e.g., due to the resilient nature of the guide extension **610***a*), passing over the locking surface **694** of the locking element **690**. The guide protrusion **620***a* is now located distal to the locking surface **694**, with the locking surface **694** limiting proximal movement of the needle cover **113** relative to the needle cover guide **143** due to engagement between the guide protrusion **620***a* (of a different portion of the guide extension **610***a*) and the locking surface **694**.
(181) It should be noted that in some examples, a respective locking element **690** may be located between each second region **642** and adjacent third region **643**. In other examples, a respective locking element **690** may be located between less than all second regions **642** and adjacent third regions **643**.
(182) Returning to FIG. **3**E, since the needle cover **113** is now limited from moving proximally from its extended position to its retracted position due to engagement with the locking element **690** of the needle cover guide **143**, the needle cover **113** cannot presently move to its retracted position to unlock the actuation member latch **450**, which in turn means that the actuation member **404** cannot presently be actuated to initiate delivery of the second dose of medicament **115**.
(183) To unlock the needle cover **113** from the locking element **690** such that it can be retracted again, the user can rotate the needle cover guide **143** relative to the needle cover **113** and body **111**, to disengage the guide protrusion(s) **620***a*, **620***b* from the respective locking element(s) **690**. This rotation may be achieved using a needle unit tool **710**, such as the needle unit tool **710** shown in FIG. **3**F.
(184) The needle unit tool **710** is a device that is releasably couplable to the needle cover guide **143**. The needle unit tool **710** comprises a tool engagement feature **770** configured to engage a corresponding tool engagement feature **670** of the needle cover guide **143** for rotating the needle cover guide **143** about the axis **144**, relative to the needle cover **113**.
(185) In some examples, the needle unit tool **710** may also be configured for performing an operation to replace the needle unit **116** coupled to the syringe **150**. For example, the needle unit tool **710** may be configured for removing (i.e., uncoupling) the needle unit **116** from the syringe **150** and/or for coupling a new needle unit **116** to the syringe **150**.
(186) Configuring the needle cover guide **143** such that it can be rotated by a needle unit tool **710** as the needle unit tool **710** performs a needle unit **116** replacement operation e.g., uncoupling and/or coupling a needle unit **116**) may be beneficial, since linking the unlocking of the needle cover **113** with the replacement of a needle unit **116** may remind/and or force the user to replace the needle unit **116** after each dose of medicament **115** has been dispensed. That is, the user will be required to replace the needle unit **116** using the needle unit tool **710** before the medicament delivery device **200** will allow a subsequent dose of medicament **115** to be dispensed. Guiding the user to replace the needle unit **116** after each dose is delivered may improve the safety of the medicament delivery device **200**, since it may reduce the likelihood of contamination and/or discomfort associated with the reuse of a needle **117**.
(187) In some examples, the same needle unit tool **710** may be used to couple and uncouple a needle unit **116** from the medicament delivery device **200**. In such examples, the needle unit tool **710** may be configured to rotate the needle cover guide **143** during only one of coupling and uncoupling of a needle unit **116** (e.g., the needle unit tool **710** may be configured to rotate the needle cover guide **143** during uncoupling of a needle unit **116** but not coupling of a needle unit **116**, or the needle unit tool **710** may be configured to rotate the needle cover guide **143** during coupling of a needle unit **116** but not uncoupling of a needle unit **116**. For example, if the needle unit **116** is configured to be both coupled and uncoupled to the medicament delivery device **200** using a screw connection, a needle unit tool **700** such as the needle unit tool **700**′ later described in relation to FIG. **7** may be used. In other examples, if the needle unit **116** is configured to be one of coupled and uncoupled to the medicament delivery device **200** using a rotational (e.g., screw) connection and the other of coupled and uncoupled to the medicament delivery device **200** using a connection that requires axial but not rotational relative rotation (e.g., a snap fit connection), the

same needle unit tool **710** may be used for both coupling and uncoupling the needle unit **116** (e.g., by performing axial but not rotational movement of the needle unit tool **710** relative to the medicament delivery device **200** to uncouple a used needle unit **116**, followed by rotational movement of the needle unit tool **710** relative to the medicament delivery device **200** to couple a new needle unit **116** to the medicament delivery device **200**, or vice versa).

(188) In other examples, one needle unit tool **710** may be used to perform uncoupling of a needle unit **116** from the medicament delivery device **200**, while a different needle unit tool **710** may be used to perform coupling of a needle unit **116** to the medicament delivery device **200**, where only one of the needle unit tools **710** may be configured to engage the needle cover guide **143** for rotation as it couples/uncouples the needle unit **116**.

(189) FIG. **3**F shows the medicament delivery device **200** of FIG. **3**E in a sixth state, after the user has removed the needle unit **116** from the medicament delivery device **200**, and an example of a needle unit tool **710**.

(190) The needle unit tool **710** may have a substantially cylindrical form, and comprises a needle unit holder **722** configured to be releasably coupled to a needle unit **116** during coupling and/or uncoupling of the needle unit **116** to the medicament delivery device **200**. The needle unit holder **722** may be configured to be releasably coupled to the needle unit **116** using any suitable means, for example by a friction fit, screw connection, adhesive (e.g., glue) connection, snap fit, magnetic connection etc.

(191) The user may have uncoupled the used needle unit **116** from the medicament delivery device **200** using the needle unit tool **710** having the tool engagement feature **770**, or by a needle unit tool **710** (or other means) without the tool engagement feature **770**. For example, the user may have first coupled the needle unit holder **722** of the needle unit tool **710** to the needle unit **116** by moving the needle unit tool **710** in a proximal direction relative to the needle unit **116** until the needle unit holder **722** engages and couples to the needle unit **116**. The needle unit holder **122** may have been inserted through a distal opening in the needle cover **113** to engage the needle unit **116**.

(192) The user may then uncoupled the needle unit **116** from the medicament delivery device **200** by moving the needle unit tool **710** relative to the medicament delivery device **200**. For example, where the needle unit **116** is coupled to the medicament delivery device **200** by a screw connection (e.g., Luer lock connection) between the connection interface **141** of the needle unit **116** and the connection interface **142** of the syringe **150**, the needle unit tool **710** may be rotated relative to the medicament delivery device **200** about the axis **144** and moved distally relative the medicament delivery device **200** to unscrew the needle unit **116** from the medicament delivery device **200**. In other examples, where the needle unit **116** is coupled to the medicament delivery device **200** by a snap fit connection between the connection interface **141** of the needle unit **116** and the connection interface **142** of the syringe **150**, the needle unit tool **710** may be moved distally relative to the medicament delivery device **200** (in some examples without relative rotation) such that the connection interface **141** of the needle unit uncouples from the connection interface **142** of the syringe **150**.

(193) Additional/alternative mechanisms and/or movements to those disclosed herein for using the needle unit tool **710** (or another means) to uncouple the needle unit **116** from the medicament delivery device **200** may be used, the selection of which may depend on the type of connection between the needle unit **116** and the medicament delivery device **200**.

(194) In this example, it shall be assumed that the user has removed the used needle unit **710** from the medicament delivery device **200** using a needle unit removal tool **710** that has not rotated the needle cover guide **143** during uncoupling of the needle unit **710** from the medicament delivery device **200**. FIG. **3**F shows that removal of the needle unit **116** has not rotated the needle cover guide **143**. As such, the needle cover **113** remains inhibited from moving from its extended position to its retracted position due to engagement with the locking element **690**.

(195) FIG. **3**G shows the medicament delivery device **200** of FIG. **3**F in a seventh state, after the

user has coupled a new needle unit **116** to the syringe **150** using a needle unit tool **710**.
(196) In some examples, the needle unit tool **710** may be provided to the user with a new needle unit **116** already coupled to the needle unit holder **772**, ready for attachment to the syringe **150**. In other examples, the user may couple the new needle unit **116** to the needle unit holder **772** prior to using the needle unit tool **710** to couple the new needle unit **116** to the syringe **150**. If the same needle unit tool **710** is being used to uncouple the used needle unit **116** and couple the new needle unit**116**, the user may remove the used needle unit **116** from the needle unit tool **710** prior to coupling a new needle unit **116** to the needle unit tool **710** (e.g., using the needle unit holder **722**).
(197) As shown in FIG. **3**G, the needle unit tool **710** has been brought into engagement with the distal end of the medicament delivery device **200** by moving the needle unit tool **710** proximally towards the distal end of the medicament delivery device **200**, such that the new needle unit **116** has passed through the opening at the distal end **120** of the needle cover **113**. The connection interface **141** of the new needle unit **116** engages the connection interface **142** of the syringe **150** (e.g., by any suitable motion disclosed herein). The tool engagement feature **770** of the needle unit tool **710** has also been brought into engagement with the tool engagement feature **670** of the needle cover guide **143**.
(198) In this example, the connection interface **141** of the new needle unit **116** is to be coupled to the connection interface **142** of the syringe **150** at least by a rotation of the needle unit tool **710** and new needle unit **116** relative to the syringe **150**, about the axis **144**. This rotation also causes the needle cover guide **143** to be rotated due to engagement between the tool engagement feature **770** of the needle unit tool **710** and the tool engagement feature **670** of the needle cover guide **143**. FIG. **3**G shows the needle cover guide **143** after it has been rotated during attachment of the new needle unit **116**.
(199) FIG. **6**D shows the configuration of the needle cover guide **143** and needle cover **113** of the medicament delivery device **200** when in its sixth state shown in FIG. **3**F, prior to rotation of the needle cover guide **143** by the needle unit tool **710**. It can be seen that the guide protrusions **620***a*, **620***b* remain in their respective third positions **653** in the respective third regions **643**.
(200) FIG. **6**D also shows the needle unit tool **710** when coupled to the needle cover guide **143**. The needle unit holder **722** and the new needle unit **116** have been hidden for clarity. The distal end of the needle cover **113** is received within the needle cover tool **710** (e.g., in a annular groove).
(201) The tool engagement feature **770** of the needle unit tool **710** has been brought into engagement with the tool engagement feature **670** of the needle cover guide **143**. In this example, the tool engagement feature **770** of the needle unit tool **710** comprises a plurality of teeth **772** arranged to engage a plurality of teeth **672** that form the tool engagement feature **670** of the needle cover guide **143**. FIG. **6**D shows the teeth **672** arranged in a circular pattern to extend distally from the distal circumferential end surface of the needle cover guide **143**. The teeth **772** are also arranged in a circular pattern, and extend proximally from a proximal-facing surface of the needle unit tool **710** (when the needle unit tool **710** is coupled to the needle cover guide **143**). The tool engagement feature **770** of the needle unit tool **710** engages the tool engagement feature **670** of the needle cover guide **143** such that a rotation of the needle unit tool **710** about the axis **144** will cause a corresponding rotation of the needle cover guide **143**.
(202) FIG. **6**E shows the configuration of the needle cover guide **143** and needle cover **113** of the medicament delivery device **200** when in its seventh state shown in FIG. **3**G, after rotation of the needle cover guide **143** by the needle unit tool **710**. As the needle cover tool **710** has been rotated about the axis **144** as indicated by the arrow **686**, the needle cover guide **143** has rotated in concert with the needle unit tool **710**, from its rotational position shown in FIG. **6**D to its rotational position shown in FIG. **6**E. It can be seen that the guide protrusions **620** have moved circumferentially around the track **128** from their respective third positions **653** in the third regions **643** of their respective track portions **630***b*, **630***e* to first positions **651** in the first regions **641** of their respective track portions **630***b*, **630***e*. The guide protrusions **620** are therefore in similar positions in FIG. **6**E

as they were in FIG. **6**A.
(203) As shown in FIG. **6**E, the rotation of the needle cover guide **143** relative to the needle cover **113** has moved the guide protrusions **620***a*, **620***b* out of engagement with their respective locking element(s) **690**, to allow the further axial movement of the needle cover **113** from the extended position to the retracted position.
(204) Returning to FIG. **3**G, the user may remove the needle unit tool **710** from the medicament delivery device **200** once the new needle unit **116** has been coupled and the needle cover guide **143** rotated, in preparation for administering a second dose of the medicament **115**.
(205) FIG. **3**H shows the medicament delivery device **200** of FIG. **3**G in a eighth state, after the user has removed the needle unit tool **710** from the medicament delivery device **200** and again pressed the distal end **120** of the needle cover **113** against an injection site (which may be the same injection site as previous, or a different injection site), to move the needle cover **113** from its extended position to its retracted position. Proximal movement of the needle cover **113** has caused the needle cover guide **143** to be rotated (e.g., in a similar manner as described previously in relation to FIGS. **6**A and **6**B, but this time by movement of the guide protrusions **620***a*, **620***b* through the respective first regions **641** of respective track portions **630***b* and **630***d*, rather than track portions **630***a* and **630***c*). Proximal movement of the needle cover **113** has also moved the actuation member latch from its locked configuration to its unlocked configuration (e.g., in a similar manner as described previously in relation to FIGS. FIGS. **4**A and **4**B).
(206) To initiate delivery of a second dose of medicament **115**, the user actuates the actuation member **404** from its first axial position to its second axial position by pushing the button **410** distally (e.g., in a similar manner as described previously in relation to FIG. **5**D). Movement of the actuation member **404** from its first position to its second position initiates delivery of the second dose of medicament by moving the ratchet mechanism **505** from its second configuration to its third configuration (e.g., in a similar manner as described previously in relation to FIGS. **5**D and **5**E).
(207) FIG. **3**I shows the medicament delivery device **200** of FIG. **3**H in a ninth state, after the user has actuated and then released the actuation member **404** to dispense the second dose of medicament **115**. FIG. **3**I shows the ratchet mechanism **505** in its third configuration, with the ratchet collar **510** prevented from moving distally by engagement between the protrusion **530***a* and the third engagement feature **540***c* of the first engagement track **545***a*.
(208) After the second dose of medicament has been delivered, the user may remove the medicament delivery device **200** from the injection site (e.g., in a similar manner as described previously in relation to FIG. **3**E), which may cause the needle cover guide **143** to be rotated such that the needle cover **113** is locked in its extended state by a further locking element **690** of the needle cover guide **143** (e.g., in a similar manner as described previously in relation to FIG. **6**C).
(209) The user may then repeat the process of replacing the needle unit **116** with another new needle unit **116** using the needle unit tool **710** (e.g., in a similar manner as described previously in relation to any of FIGS. **3**F, **3**G, **6**D and **6**E), rotating the needle cover guide **143** in the process and thereby unlocking the needle cover **113** such that it can be moved proximally.
(210) To deliver a third dose of medicament **115**, the user again presses the distal end **120** of the needle cover **113** against an injection site (which may be the same injection site(s) as previous, or a different injection site), to move the needle cover **113** from its extended position to its retracted position. Proximal movement of the needle cover **113** again causes the needle cover guide **143** to be rotated (e.g., in a similar manner as described previously in relation to FIGS. **6**A and **6**B) and moves the actuation member latch **450** from its locked configuration to its unlocked configuration (e.g., in a similar manner as described previously in relation to FIGS. **4**A and **4**B).
(211) To initiate delivery of the third dose of medicament **115**, the user actuates the actuation member **404** from its first axial position to its second axial position by pushing the button **410** distally (e.g., in a similar manner as described previously in relation to FIGS. **5**E and **5**F).

Movement of the actuation member **404** from its first position to its second position initiates delivery of the third dose of medicament **115** by moving the ratchet mechanism **505** from its third configuration to its fourth configuration (e.g., in a similar manner as described previously in relation to FIGS. **5**F and **5**G), releasing the ratchet collar **510** for axial movement to cause the third dose of medicament **115** to be dispensed.

(212) FIG. **3**J shows the medicament delivery device **200** of FIG. **3**I in a tenth state, after the user has dispensed the third dose of medicament **115**. In this example, the third dose of medicament **115** is the final dose of medicament to be administered using the medicament delivery device **200**. The ratchet mechanism **505** is in its fourth configuration.

(213) FIG. **3**J shows the protrusion **530***a* having engaged a fourth engagement element **540***a* to limit further distal movement of the ratchet collar **510**. However, this is not meant to be limiting. In one or more other examples, the protrusion **530***a* does not engage a fourth engagement element **540***a* to limit further distal movement of the ratchet collar **510**. Instead, further distal movement of the ratchet collar **510** may limited by a different mechanism, for example the drive member may no longer provide a biasing force to rotate the rotary collar **119** after the final dose has been dispensed, or the plunger **121** may engage a stop feature that limits further distal movement of the plunger **121**

(214) FIG. **3**K shows the medicament delivery device **200** of FIG. **3**J in a eleventh state, after the user has removed the medicament delivery device **200** from the injection site and the needle cover **113** has moved distally from its retracted position shown in FIG. **3**J to its extended position shown in FIG. **3**K (e.g., due to biasing by the needle cover biasing member **118**). After the needle cover **113** has moved distally from its retracted position to its extended position, subsequent movement of the needle cover **113** from the extended position to the retracted position may once again be limited (e.g., by a locking element **690**). However, unlike in previous instances in which the needle cover guide **143** has been rotated using the needle unit tool **710** to allow the needle cover **113** to be moved proximally again, the needle cover guide **143** is now inhibited from being rotated by to unlock the needle cover **113**, as shown in FIG. **6**F. The needle cover **113** therefore remains in a locked, extended position, protecting the user from the used needle **117**.

(215) FIG. **6**F shows the needle cover guide **143** of the medicament delivery device **200** of FIG. **3**K. Distal movement of the guide protrusion **620** as the needle cover **113** has moved from its retracted position to its extended position after delivery of the third dose has caused the guide protrusion **620** to engage a locking element **690** arranged between the third track portion **630***c* and the fourth track portion **630***d* (e.g., in a similar manner as described previously in relation to FIG. **6**C). However, rotation of the needle cover **113** relative to the needle sleeve **113** is now limited (e.g., prevented) by a rotation stop element **695** (e.g., a wall) in the fourth track portion **630***d*). An attempt to rotate the needle cover guide **143** relative to the needle cover **113** (e.g., using a needle unit tool **710** as described previously) will cause the guide protrusion **620** to engage the rotation stop element **695**, limiting rotation of the needle cover **113** relative to the needle sleeve **113**. The needle cover guide **143** may therefore no longer be rotated to unlock the needle cover **113** for proximal movement.

(216) The user may now safely dispose the medicament delivery device **200**.

(217) FIG. **7** shows an alternative embodiment of the needle unit tool **710**′, coupled to a needle cover guide **143**′ (which may be similar or identical to the needle cover guide **143**). The needle unit tool **710**′ may share one or more feature with any needle unit tool **710** disclosed previously. However, the needle unit tool **710**′ has a tool engagement feature **770**′ comprising a ratchet gear rack formed from a plurality of asymmetrical ratchet teeth **774** arranged in a continuous circular pattern on a proximal-facing surface of the needle unit tool **710**′.

(218) Each tooth of the ratchet teeth **774** comprises a gently ramped surface **776** that each extend in a plane substantially normal to the axis **144**, and a contact surface **778** that each extend in a plane substantially parallel to the axis **144**. The ratchet gear rack of the needle unit tool **710**′ is configured to engage a corresponding tool engagement feature **670**′ of the needle cover guide **143**′, also in the

form of a ratchet gear rack comprising a plurality of asymmetrical ratchet teeth **674**. The ratchet teeth **674** are arranged in a continuous circular pattern on a distal-facing surface of the needle cover guide **143**′. Each tooth of the ratchet teeth **674** comprises a gently ramped surface **676** that each extend in a plane substantially normal to the axis **144**, and a contact surface **678** that each extend in a plane substantially parallel to the axis **144**. The ratchet teeth **774** of the needle unit tool **710**′ and the ratchet teeth **674** of the needle cover guide **143**′ are arranged to engage with each other when the needle unit tool **710**′ is coupled to the needle cover guide **143**′, with the ramped surfaces **776** each engaging a respective ramped surface **676** and the contact surfaces **778** each engaging a respective contact surface **678**.

(219) The tool engagement feature **770**′ of the needle unit tool **710**′ and the tool engagement feature **670**′ of the needle cover guide **143** are therefore configured such that, when the tool engagement feature **770**′ and tool engagement feature **670**′ are coupled as shown in FIG. **7**, rotation of the needle cover tool **710**′ relative to the body **111** in a first direction about the axis **144** (e.g. as shown by arrow **790**) causes the needle cover guide **143**′ to rotate in concert with the needle cover tool **710**′, but rotation of the needle cover tool **710**′ relative to the body **111** in a second direction opposite to the first direction does not cause the needle cover guide **143**′ to substantially rotate relative to the body **111** (due to the ramped surfaces **676**, **776** sliding over one another). Such a mechanism can allow the same needle unit tool **710**′ to be used for both coupling and uncoupling needle units **116** from the medicament delivery device **200** by screwing and unscrewing the needle units **116**, but ensures that the needle cover guide **143**′ is only rotated by the rotation of the needle unit tool **710**′ in one of the two rotations (e.g., only during screwing on of a new needle unit **116**).

(220) A method **800** of using a medicament delivery device, which may be the medicament delivery device **200** described in relation to any of FIGS. **3**A-**3**K, **4**A-C, **5**A-**5**G, **6**A-**6**F and/or FIG. **7** will now be described with reference to FIG. **8**.

(221) At an optional operation **810**, a cap **12** of the medicament delivery device **200** is removed (if present).

(222) At operation **820**, a needle cover **113** of the medicament delivery device is moved from an extended position to a retracted position. The needle cover **113** may be moved from the extended position to the retracted position by pressing the needle cover **113** against an injection site.

(223) At operation **830**, an actuation member **404** of the medicament delivery device is actuated to dispense a first dose of medicament (e.g., as previously described herein).

(224) At operation **840**, the needle cover **113** of the medicament delivery device is moved from the retracted position to the extended position (e.g., as previously described herein). The needle cover **113** may be moved from the retracted position to the extended position by removing the needle cover **113** from the injection site. Responsive to the needle cover **113** moving from the retracted position to the extended position, the needle cover **113** may be limited from moving from its extended position to its retracted position.

(225) At operation **850**, a needle cover guide **143** of the medicament delivery device is rotated to allow the needle cover **113** to move from its extended position to its retracted position. The needle cover guide **143** may be rotated using a needle unit tool **710**, **710**′, for example during a needle unit replacement operation.

(226) At operation **860**, the needle cover **113** of the medicament delivery device is moved from the extended position to a retracted position. The needle cover **113** may be moved from the extended position to the retracted position by pressing the needle cover **113** against an injection site.

(227) At operation **870**, the actuation member **404** of the medicament delivery device is actuated to dispense a subsequent (e.g., second, third, . . . , etc.) dose of medicament (e.g., as previously described herein).

(228) At optional operation **880**, the needle cover **113** of the medicament delivery device is moved from the retracted position to the extended position (e.g., as previously described herein). The needle cover **113** may be moved from the retracted position to the extended position by removing

the needle cover **113** from the injection site. Responsive to the needle cover **113** moving from the retracted position to the extended position, the needle cover **113** may be limited from moving from its extended position to its retracted position.
(229) Optionally, after operation **880**, operations **850** to **880** may be repeated one or more additional times in order to dispense further doses of medicament, if the medicament delivery device **200** is so configured (e.g., if rotation of the needle cover guide **143** is not yet limited by a rotation stop element **695**).
(230) At operation **890** the method **800** ends. Further rotation of the needle cover guide **143** may be limited by a rotation stop element **695**.
(231) While various aspects of this disclosure have been described as suitable for delivering a plurality of doses of a medicament into a subject, it should be understood that aspects of this disclosure may additionally/alternatively be used to dispense one or more doses of medicament without the medicament actually being injected into a subject, such as during a priming operation of the medicament delivery device. For example, in accordance with one or more aspects of this disclosure, a user may initiate movement of the medicament delivery mechanism by pushing the medicament delivery device into an injection site that is not part of a human or animal body (such as a block of rubber or foam), to trigger dispensing of a first dose of medicament into the non-human/non-animal injection site, wherein this first dose may be a priming dose that is not to be administered to a human or animal subject. A second priming dose may subsequently be administered to the non-human/non-animal injection site by the user removing and then reinserting the medicament delivery device into the human/non-animal injection site in accordance with one or more aspects disclosed herein. Further priming doses may be administered in a similar manner. Such a priming operation may be performed to flush the medicament through the syringe and/or needle, and/or as a test to check that the medicament delivery device is operating correctly.
(232) While it has generally been described herein that the medicament delivery device **200** comprises both the ratchet mechanism **505** and the needle cover guide **143**, it should be understood that in other examples the medicament delivery device **200** may comprise only one of the ratchet mechanism **505** and the needle cover guide **143**. For example, the medicament delivery device **200** may employ a ratchet mechanism **505** for allowing discrete doses of medicament **115** to be dispensed, without also employing a needle cover guide **143** for locking the needle cover **113** after the delivery of each dose.
(233) Alternatively, the medicament delivery device **200** may employ a needle cover guide **143** for locking the needle cover **113** after the needle cover **113** has moved from its retracted to its extended position, without also employing a ratchet mechanism **505** for allowing discrete doses of medicament **115** to be dispensed. In other words, in some examples the concept of the ratchet mechanism **505** and the needle cover guide **143** may be separable.
(234) In any of the embodiments disclosed herein, the medicament delivery device **200** may additionally have a cap **12** which covers the distal end of the needle cover **113**. The cap **12** may be coupled to the remainder of the medicament delivery device **200** (e.g., to the body **111**) when the medicament delivery device **100** is in its initial state corresponding to FIG. **3**A. The cap **12** may be removed from the remainder of the medicament delivery device **200** by the user, prior to injection. Removal of the cap **12** may also remove a rigid needle shield (RNS) surrounding the needle **117**, wherein the RNS is removed with the cap **12** (e.g., due to engagement between the RNS and the cap **12**).
(235) It has generally been described herein that the needle cover guide **143** is rotated using a needle unit tool **710**, during an operation of replacing (e.g. coupling or uncoupling) a needle unit **116**. However, it should be understood that in other examples the needle cover guide **143** may be configured to be rotated in a different manner. For example, the needle cover guide **143** may be configured to be rotated during an operation that is not replacing the needle unit **116** (e.g., during attachment and/or removal of a cap **12** of the medicament delivery device **200**, wherein the cap **12**

comprises an engagement feature configured to engage the tool engagement feature **670** of needle cover guide for rotating the needle cover guide **143** as the cap **12** is rotated). In yet other examples, at least a portion of the needle cover guide **143** may be accessible to a user such that user may directly rotate the needle cover guide **143** with a finger.

(236) It has generally been described herein that the engagement elements **540** each take the form of a projection such as a ridge, however this is not meant to be limiting. For example, in one or more alternative examples, the engagement elements **540** each take the form of a different type of projection to a ridge, or they take a form different to a projection, such as a recess. In each case, the engagement elements **540** each take a form that can be engaged by the protrusion **530** of the ratchet collar **510** to limit axial movement of the ratchet collar **510**.

(237) It has generally been described herein that the engagement elements **540** of each engagement track **545** are evenly spaced in the axial direction, which may lead to each dose of medicament being equal in size. However, it should be understood that in one or more other embodiments, the distance in the axial direction between each engagement element **540** in an engagement track **545** may vary between engagement elements **540**, such that a different size of dose is dispensed as the protrusion **530** moves between the different engagement elements **540**. For example, first, second and third engagement elements **540***a*, **540***b*, **540***c* may be arranged such that the distance along the axis **144** between the first engagement element **540***a* and the second engagement element **540***b* is greater than the distance along the axis **144** between the second engagement element **540***b* and the third engagement element **540***c*. As such, the first dose dispensed as the protrusion **530** of the ratchet collar **510** moves from the first engagement element **540***a* to the second engagement element **540***b* may be greater in size than the second dose dispensed as the protrusion **530** of the ratchet collar **510** moves from the second engagement element **540***b* to the third engagement element **540***c*, with the size of each dose being proportional to the distance between the two engagement elements used to dispense the dose (assuming the dose dispensed by the medicament delivery mechanism **180** is proportional to the axial distance moved by the ratchet collar **510**).

(238) It has generally been described herein that the actuation member **404** comprises a button **410**, however this is not meant to be limiting. For example, in one or more alternative examples, the button **410** may be replaced by a slider or a rotatable dial, wherein the slider/rotatable dial is coupled to the arm(s) **420** of the actuation member **404** such that actuation of the actuation member **404** (e.g., via sliding of the slider or rotation of the dial by a user) causes distal and/or proximal movement of the arm(s) **420** for triggering delivery of a dose of medicament, in a similar manner as described elsewhere.

(239) It should be understood that the actuation member **404** may be located at a different position relative to the body **111** to that described in relation to FIGS. **3**A-**3**K. For example, in other examples the button **410** (or slider or dial) may be located at a different location than the proximal end of the body **111**, for example at distal end of the body **111**.

(240) It has generally been described herein that the axially movable ratchet shuttle is in the form of a ratchet collar **510**. However, it should be understood that in other examples, a different form of ratchet shuttle could be used that comprises a flexible arm **520** and protrusion **530**, and that can be moved axially by the drive member in a similar manner to the ratchet collar **510**, but does not have the shape of a collar.

(241) The terms “drug” or “medicament” are used synonymously herein and describe a pharmaceutical formulation containing one or more active pharmaceutical ingredients or pharmaceutically acceptable salts or solvates thereof, and optionally a pharmaceutically acceptable carrier. An active pharmaceutical ingredient (“API”), in the broadest terms, is a chemical structure that has a biological effect on humans or animals. In pharmacology, a drug or medicament is used in the treatment, cure, prevention, or diagnosis of disease or used to otherwise enhance physical or mental well-being. A drug or medicament may be used for a limited duration, or on a regular basis for chronic disorders.

(242) As described below, a drug or medicament can include at least one API, or combinations thereof, in various types of formulations, for the treatment of one or more diseases. Examples of API may include small molecules having a molecular weight of 500 Da or less; polypeptides, peptides and proteins (e.g., hormones, growth factors, antibodies, antibody fragments, and enzymes); carbohydrates and polysaccharides; and nucleic acids, double or single stranded DNA (including naked and cDNA), RNA, antisense nucleic acids such as antisense DNA and RNA, small interfering RNA (siRNA), ribozymes, genes, and oligonucleotides. Nucleic acids may be incorporated into molecular delivery systems such as vectors, plasmids, or liposomes. Mixtures of one or more drugs are also contemplated.

(243) The drug or medicament may be contained in a primary package or "drug container" adapted for use with a drug delivery device. The drug container may be, e.g., a cartridge, syringe, reservoir, or other solid or flexible vessel configured to provide a suitable chamber for storage (e.g., short- or long-term storage) of one or more drugs. For example, in some instances, the chamber may be designed to store a drug for at least one day (e.g., 1 to at least 30 days). In some instances, the chamber may be designed to store a drug for about 1 month to about 2 years. Storage may occur at room temperature (e.g., about 20° C.), or refrigerated temperatures (e.g., from about −4° C. to about 4° C.). In some instances, the drug container may be or may include a dual-chamber cartridge configured to store two or more components of the pharmaceutical formulation to-be-administered (e.g., an API and a diluent, or two different drugs) separately, one in each chamber. In such instances, the two chambers of the dual-chamber cartridge may be configured to allow mixing between the two or more components prior to and/or during dispensing into the human or animal body. For example, the two chambers may be configured such that they are in fluid communication with each other (e.g., by way of a conduit between the two chambers) and allow mixing of the two components when desired by a user prior to dispensing. Alternatively, or in addition, the two chambers may be configured to allow mixing as the components are being dispensed into the human or animal body.

(244) The drugs or medicaments contained in the drug delivery devices as described herein can be used for the treatment and/or prophylaxis of many different types of medical disorders. Examples of disorders include, e.g., diabetes mellitus or complications associated with diabetes mellitus such as diabetic retinopathy, thromboembolism disorders such as deep vein or pulmonary thromboembolism. Further examples of disorders are acute coronary syndrome (ACS), angina, myocardial infarction, cancer, macular degeneration, inflammation, hay fever, atherosclerosis and/or rheumatoid arthritis. Examples of APIs and drugs are those as described in handbooks such as Rote Liste 2014, for example, without limitation, main groups 12 (anti-diabetic drugs) or 86 (oncology drugs), and Merck Index, 15th edition.

(245) Examples of APIs for the treatment and/or prophylaxis of type 1 or type 2 diabetes mellitus or complications associated with type 1 or type 2 diabetes mellitus include an insulin, e.g., human insulin, or a human insulin analogue or derivative, a glucagon-like peptide (GLP-1), GLP-1 analogues or GLP-1 receptor agonists, or an analogue or derivative thereof, a dipeptidyl peptidase-4 (DPP4) inhibitor, or a pharmaceutically acceptable salt or solvate thereof, or any mixture thereof. As used herein, the terms "analogue" and "derivative" refers to a polypeptide which has a molecular structure which formally can be derived from the structure of a naturally occurring peptide, for example that of human insulin, by deleting and/or exchanging at least one amino acid residue occurring in the naturally occurring peptide and/or by adding at least one amino acid residue. The added and/or exchanged amino acid residue can either be codable amino acid residues or other naturally occurring residues or purely synthetic amino acid residues. Insulin analogues are also referred to as "insulin receptor ligands". In particular, the term, derivative" refers to a polypeptide which has a molecular structure which formally can be derived from the structure of a naturally occurring peptide, for example that of human insulin, in which one or more organic substituent (e.g., a fatty acid) is bound to one or more of the amino acids. Optionally, one or more

amino acids occurring in the naturally occurring peptide may have been deleted and/or replaced by other amino acids, including non-codeable amino acids, or amino acids, including non-codeable, have been added to the naturally occurring peptide.
(246) Examples of insulin analogues are Gly (A21), Arg (B31), Arg (B32) human insulin (insulin glargine); Lys (B3), Glu (B29) human insulin (insulin glulisine); Lys (B28), Pro (B29) human insulin (insulin lispro); Asp (B28) human insulin (insulin aspart); human insulin, wherein proline in position B28 is replaced by Asp, Lys, Leu, Val or Ala and wherein in position B29 Lys may be replaced by Pro; Ala (B26) human insulin; Des (B28-B30) human insulin; Des (B27) human insulin and Des (B30) human insulin.
(247) Examples of insulin derivatives are, for example, B29-N-myristoyl-des (B30) human insulin, Lys (B29) (N-tetradecanoyl)-des (B30) human insulin (insulin detemir, Levemir®); B29-N-palmitoyl-des (B30) human insulin; B29-N-myristoyl human insulin; B29-N-palmitoyl human insulin; B28-N-myristoyl LysB28ProB29 human insulin; B28-N-palmitoyl-LysB28ProB29 human insulin; B30-N-myristoyl-ThrB29LysB30 human insulin; B30-N-palmitoyl-ThrB29LysB30 human insulin; B29-N—(N-palmitoyl-gamma-glutamyl)-des (B30) human insulin, B29-N-omega-carboxypentadecanoyl-gamma-L-glutamyl-des (B30) human insulin (insulin degludec, Tresiba®); B29-N—(N-lithocholyl-gamma-glutamyl)-des (B30) human insulin; B29-N-(ω-carboxyheptadecanoyl)-des (B30) human insulin and B29-N-(ω-carboxyheptadecanoyl) human insulin.
(248) Examples of GLP-1, GLP-1 analogues and GLP-1 receptor agonists are, for example, Lixisenatide (Lyxumia®), Exenatide (Exendin-4, Byetta®, Bydureon®, a 39 amino acid peptide which is produced by the salivary glands of the Gila monster), Liraglutide (Victoza®), Semaglutide, Taspoglutide, Albiglutide (Syncria®), Dulaglutide (Trulicity®), rExendin-4, CJC-1134-PC, PB-1023, TTP-054, Langlenatide/HM-11260C (Efpeglenatide), HM-15211, CM-3, GLP-1 Eligen, ORMD-0901, NN-9423, NN-9709, NN-9924, NN-9926, NN-9927, Nodexen, Viador-GLP-1, CVX-096, ZYOG-1, ZYD-1, GSK-2374697, DA-3091, MAR-701, MAR709, ZP-2929, ZP-3022, ZP-DI-70, TT-401 (Pegapamodtide), BHM-034. MOD-6030, CAM-2036, DA-15864, ARI-2651, ARI-2255, Tirzepatide (LY3298176), Bamadutide (SAR425899), Exenatide-XTEN and Glucagon-Xten.
(249) An example of an oligonucleotide is, for example: mipomersen sodium (Kynamro®), a cholesterol-reducing antisense therapeutic for the treatment of familial hypercholesterolemia or RG012 for the treatment of Alport syndrom.
(250) Examples of DPP4 inhibitors are Linagliptin, Vildagliptin, Sitagliptin, Denagliptin, Saxagliptin, Berberine.
(251) Examples of hormones include hypophysis hormones or hypothalamus hormones or regulatory active peptides and their antagonists, such as Gonadotropine (Follitropin, Lutropin, Choriongonadotropin, Menotropin), Somatropine (Somatropin), Desmopressin, Terlipressin, Gonadorelin, Triptorelin, Leuprorelin, Buserelin, Nafarelin, and Goserelin.
(252) Examples of polysaccharides include a glucosaminoglycane, a hyaluronic acid, a heparin, a low molecular weight heparin or an ultra-low molecular weight heparin or a derivative thereof, or a sulphated polysaccharide, e.g. a poly-sulphated form of the above-mentioned polysaccharides, and/or a pharmaceutically acceptable salt thereof. An example of a pharmaceutically acceptable salt of a poly-sulphated low molecular weight heparin is enoxaparin sodium. An example of a hyaluronic acid derivative is Hylan G-F 20 (Synvisc®), a sodium hyaluronate.
(253) The term “antibody”, as used herein, refers to an immunoglobulin molecule or an antigen-binding portion thereof. Examples of antigen-binding portions of immunoglobulin molecules include F(ab) and F(ab′)2 fragments, which retain the ability to bind antigen.
(254) The antibody can be polyclonal, monoclonal, recombinant, chimeric, de-immunized or humanized, fully human, non-human, (e.g., murine), or single chain antibody. In some embodiments, the antibody has effector function and can fix complement. In some embodiments,

the antibody has reduced or no ability to bind an Fc receptor. For example, the antibody can be an isotype or subtype, an antibody fragment or mutant, which does not support binding to an Fc receptor, e.g., it has a mutagenized or deleted Fc receptor binding region. The term antibody also includes an antigen-binding molecule based on tetravalent bispecific tandem immunoglobulins (TBTI) and/or a dual variable region antibody-like binding protein having cross-over binding region orientation (CODV).

(255) The terms “fragment” or “antibody fragment” refer to a polypeptide derived from an antibody polypeptide molecule (e.g., an antibody heavy and/or light chain polypeptide) that does not comprise a full-length antibody polypeptide, but that still comprises at least a portion of a full-length antibody polypeptide that is capable of binding to an antigen. Antibody fragments can comprise a cleaved portion of a full length antibody polypeptide, although the term is not limited to such cleaved fragments. Antibody fragments that are useful in the present disclosure include, for example, Fab fragments, F(ab′)2 fragments, scFv (single-chain Fv) fragments, linear antibodies, monospecific or multispecific antibody fragments such as bispecific, trispecific, tetraspecific and multispecific antibodies (e.g., diabodies, triabodies, tetrabodies), monovalent or multivalent antibody fragments such as bivalent, trivalent, tetravalent and multivalent antibodies, minibodies, chelating recombinant antibodies, tribodies or bibodies, intrabodies, nanobodies, small modular immunopharmaceuticals (SMIP), binding-domain immunoglobulin fusion proteins, camelized antibodies, and VHH containing antibodies. Additional examples of antigen-binding antibody fragments are known in the art.

(256) The terms “Complementarity-determining region” or “CDR” refer to short polypeptide sequences within the variable region of both heavy and light chain polypeptides that are primarily responsible for mediating specific antigen recognition. The term “framework region” refers to amino acid sequences within the variable region of both heavy and light chain polypeptides that are not CDR sequences, and are primarily responsible for maintaining correct positioning of the CDR sequences to permit antigen binding. Although the framework regions themselves typically do not directly participate in antigen binding, as is known in the art, certain residues within the framework regions of certain antibodies can directly participate in antigen binding or can affect the ability of one or more amino acids in CDRs to interact with antigen.

(257) Examples of antibodies are anti PCSK-9 mAb (e.g., Alirocumab), anti IL-6 mAb (e.g., Sarilumab), and anti IL-4 mAb (e.g., Dupilumab).

(258) Pharmaceutically acceptable salts of any API described herein are also contemplated for use in a drug or medicament in a drug delivery device. Pharmaceutically acceptable salts are for example acid addition salts and basic salts.

(259) Those of skill in the art will understand that modifications (additions and/or removals) of various components of the APIs, formulations, apparatuses, methods, systems and embodiments described herein may be made without departing from the full scope and spirit of the present disclosure, which encompass such modifications and any and all equivalents thereof.

(260) An example drug delivery device may involve a needle-based injection system as described in Table 1 of section 5.2 of ISO 11608-1: 2014 (E). As described in ISO 11608-1: 2014 (E), needle-based injection systems may be broadly distinguished into multi-dose container systems and single-dose (with partial or full evacuation) container systems. The container may be a replaceable container or an integrated non-replaceable container.

(261) As further described in ISO 11608-1: 2014 (E), a multi-dose container system may involve a needle-based injection device with a replaceable container. In such a system, each container holds multiple doses, the size of which may be fixed or variable (pre-set by the user). Another multi-dose container system may involve a needle-based injection device with an integrated non-replaceable container. In such a system, each container holds multiple doses, the size of which may be fixed or variable (pre-set by the user).

(262) As further described in ISO 11608-1: 2014 (E), a single-dose container system may involve a

needle-based injection device with a replaceable container. In one example for such a system, each container holds a single dose, whereby the entire deliverable volume is expelled (full evacuation). In a further example, each container holds a single dose, whereby a portion of the deliverable volume is expelled (partial evacuation). As also described in ISO 11608-1: 2014 (E), a single-dose container system may involve a needle-based injection device with an integrated non-replaceable container. In one example for such a system, each container holds a single dose, whereby the entire deliverable volume is expelled (full evacuation). In a further example, each container holds a single dose, whereby a portion of the deliverable volume is expelled (partial evacuation).

(263) Those of skill in the art will understand that modifications (additions and/or removals) of various components of the embodiments described herein may be made without departing from the full scope and spirit of the present disclosure, which encompass such modifications and any and all equivalents thereof.

LIST OF REFERENCE NUMBERS

(264) **10**—drug delivery device **11**—housing **11***a*—window **12**—cap assembly **13**—needle sleeve **14**—reservoir **15**—medicament **17**—needle **20**—distal region **21**—proximal region **22**—button **23**—bung or piston **100**—medicament delivery device **111**—body **113**—needle cover **114**—container **115**—medicament **116**—needle unit **117**—needle **118**—needle cover biasing member **119**—rotary collar **120**—distal end (of the needle cover) **121**—plunger **122**—external screw thread **123**—bung or piston **124**—drive member **125**—internal screw thread **126**—arm **127**—protrusion (of needle cover guide) **128**—track (of needle cover guide) **130**—proximal end (of body) **131**—distal end (of body) **140**—distal end (of needle) **141**—connection interface (of needle unit) **142**—connection interface (of syringe) **143**, **143**′—needle cover guide **144**—axis **150**—syringe **152**—arrow **171**—spring **180**—medicament delivery mechanism **200**—medicament delivery device **400**—medicament delivery device **404**—actuation member **410**—button **412**—proximal actuation surface (of button) **420**—arm (of actuation member) **430**—apertures (of arm) **432**—distal-facing surface (of aperture) **434**—proximal-facing surface (of aperture) **440**—guide surfaces (of arm) **450**—actuation member latch **452**—flexible extension (of actuation member latch) **454**—projection (of actuation member latch) **456**—recess (of latch element) **458**—latch element **460**—recess (of needle cover) **462**—proximal-facing surface (of recess of latch element) **464**—distal-facing surface (of projection) **466**—proximal-facing surface (of recess of needle cover) **500**—medicament delivery device **505**—ratchet mechanism **510**—ratchet collar **520**—flexible arm (of ratchet collar) **530**—protrusion (of ratchet collar) **532**—engaging surface (of ratchet collar) **534**—ramped surface (of ratchet collar) **540**—engagement elements **542**—engaging surface (of engagement element) **545**—engagement track **610**—guide extensions **620**—guide protrusion **630***a*-**630***f*—track portion(s) **641**—first region **642**—second region **643**—third region **651**—first position **652**—second position **653**—third position **654**—fourth position **660**—surface (of second region) **670**, **670**′—tool engagement feature (of needle cover guide) **672**—teeth (of needle cover guide) **674**—teeth (of ratchet gear rack) **676**—ramped surface (of teeth) **678**—contact surface (of teeth) **680**—angled proximal wall (of first region) **682**—arrow **684**—arrow **686**—arrow **690**—locking element **692**—locking surface (of locking element) **694**—ramped surface (of locking element) **695**—rotation stop element **710**, **710**′—needle unit tool **722**—needle unit holder **770**, **770**′—tool engagement feature (of needle unit tool) **772**—teeth (of needle unit tool) **774**—teeth (of ratchet gear rack) **776**—ramped surface (of teeth) **778**—contact surface (of teeth) **790**—arrow **800**—method **810**—first method operation **820**—second method operation **830**—third method operation **840**—fourth method operation **850**—fifth method operation **860**—sixth method operation **870**—seventh method operation **880**—eighth method operation **890**—ninth method operation

Claims

1. A medicament delivery device comprising: a body having a proximal end and a distal end arranged along a first axis, the body configured to hold a container containing a medicament; a needle cover axially movable relative to the body between an extended position and a retracted position; a medicament delivery mechanism comprising a plunger and a drive member, the drive member configured to move the plunger along the first axis to dispense the medicament from the container; an actuation member configured to be actuated relative to the body; and a ratchet mechanism coupled to the medicament delivery mechanism and sequentially movable between a first configuration, a second configuration and a third configuration, wherein the ratchet mechanism comprises: a ratchet shuttle axially movable by the drive member and comprising a protrusion, and an engagement track comprising a first engagement element and a second engagement element aligned along an inner surface of the body and along a second axis parallel to the first axis, wherein the protrusion is configured to engage the first engagement element when the ratchet mechanism is in the first configuration, to limit axial movement of the ratchet shuttle by the drive member, wherein the actuation member and the ratchet mechanism are arranged such that: a first actuation of the actuation member moves the ratchet mechanism from the first configuration to the second configuration to cause a first dose of the medicament to be dispensed, and a second actuation of the actuation member, subsequent to the first actuation, moves the ratchet mechanism from the second configuration to the third configuration to cause a second dose of the medicament to be dispensed.
2. The medicament delivery device of claim 1, wherein the actuation member comprises a button arranged to be pushed a first time to provide the first actuation and pushed a second time to provide the second actuation.
3. The medicament delivery device of claim 1, wherein the actuation member is movable between a first position and a second position, wherein the first actuation of the actuation member comprises a first movement of the actuation member from the first position to the second position, and wherein the second actuation of the actuation member comprises a second movement of the actuation member from the first position to the second position, the second movement subsequent to the first movement.
4. The medicament delivery device of claim 1, wherein the protrusion is configured to engage the second engagement element when the ratchet mechanism is in the second configuration, to limit axial movement of the ratchet shuttle by the drive member.
5. The medicament delivery device of claim 1, further comprising an arm that comprises a plurality of apertures and a plurality of guide surfaces arranged such that the apertures and guide surfaces alternate in an axial direction.
6. The medicament delivery device of claim 1, wherein the ratchet shuttle is a ratchet collar.
7. The medicament delivery device of claim 1, wherein the actuation member and ratchet mechanism are configured such that: the first actuation of the actuation member disengages the protrusion from the first engagement element to cause the protrusion to move axially to the second engagement element; and the second actuation of the actuation member disengages the protrusion from the second engagement element to cause the protrusion to move axially.
8. The medicament delivery device of claim 1, wherein: when in the extended position, a distal end of the needle cover is distal to a distal end of a needle; and when in the retracted position, the distal end of the needle is distal to the distal end of the needle cover.
9. The medicament delivery device of claim 8, wherein the medicament delivery device further comprises a needle cover biasing member configured to bias the needle cover distally.
10. The medicament delivery device of claim 8, further comprising a needle cover guide having a track configured to be engaged by a guide protrusion of the needle cover such that an axial movement of the needle cover from the extended position to the retracted position causes a rotation of the needle cover guide relative to the needle cover.

11. The medicament delivery device of claim 10, wherein the track comprises a locking element arranged such that an axial movement of the needle cover from the retracted position to the extended position subsequent to the rotation of the needle cover guide engages the guide protrusion with the locking element, to limit a further axial movement of the needle cover from the extended position to the retracted position.
12. The medicament delivery device of claim 11, wherein a further rotation of the needle cover guide relative to the needle cover disengages the guide protrusion from the locking element to allow the further axial movement of the needle cover from the extended position to the retracted position.
13. The medicament delivery device of claim 12, further comprising: a needle unit comprising a needle; a needle unit tool releasably coupled to the needle cover guide; wherein the medicament delivery device is configured to be releasably coupled to the needle unit comprising a needle, and wherein the needle cover guide is configured such that the further rotation is performed as the needle unit is coupled or uncoupled from the medicament delivery device by the needle unit tool.
14. The medicament delivery device of claim 1, further comprising an actuation member latch movable between a locked configuration, in which actuation of the actuation member is limited, and an unlocked configuration, in which actuation of the actuation member is allowed.
15. The medicament delivery device of claim 14, wherein the actuation member latch is configured to be moved from the locked configuration to the unlocked configuration by movement of the needle cover from the extended position to the retracted position.
16. The medicament delivery device of claim 1, wherein the actuation member and the ratchet mechanism are arranged such that: a third actuation of the actuation member moves the ratchet mechanism from the third configuration to a fourth configuration to cause a third dose of the medicament to be dispensed.
17. The medicament delivery device according to claim 1, further comprising the medicament.
18. A system comprising: a medicament delivery device comprising: a body having a proximal end and a distal end arranged along a first axis, the body configured to hold a container containing a medicament; a needle cover axially movable relative to the body between an extended position and a retracted position; a medicament delivery mechanism comprising a plunger and a drive member, the drive member configured to move the plunger along the first axis to dispense the medicament from the container; an actuation member configured to be actuated relative to the body; and a ratchet mechanism coupled to the medicament delivery mechanism and sequentially movable between a first configuration, a second configuration and a third configuration, wherein the ratchet mechanism comprises: a ratchet shuttle axially movable by the drive member and comprising a protrusion, and an engagement track comprising a first engagement element and a second engagement element aligned along an inner surface of the body and along a second axis parallel to the first axis, wherein the protrusion is configured to engage the first engagement element when the ratchet mechanism is in the first configuration, to limit axial movement of the ratchet shuttle by the drive member, wherein the actuation member and the ratchet mechanism are arranged such that: a first actuation of the actuation member moves the ratchet mechanism from the first configuration to the second configuration to cause a first dose of the medicament to be dispensed, and a second actuation of the actuation member, subsequent to the first actuation, moves the ratchet mechanism from the second configuration to the third configuration to cause a second dose of the medicament to be dispensed; a needle unit releasably couplable to the medicament delivery device; and a needle unit tool for coupling the needle unit to the medicament delivery device or uncoupling the needle unit from the medicament delivery device.
19. A method of operating a medicament delivery device, wherein the medicament delivery device comprises: a body having a proximal end and a distal end arranged along a first axis, the body configured to hold a container containing a medicament; a needle cover axially movable relative to the body between an extended position and a retracted position; a medicament delivery mechanism

comprising a plunger and a drive member, the drive member configured to move the plunger along the first axis to dispense the medicament from the container; an actuation member configured to be actuated relative to the body; and a ratchet mechanism coupled to the medicament delivery mechanism and sequentially movable between a first configuration, a second configuration and a third configuration, wherein the ratchet mechanism comprises: a ratchet shuttle axially movable by the drive member and comprising a protrusion, and an engagement track comprising a first engagement element and a second engagement element aligned along an inner surface of the body and along a second axis parallel to the first axis, wherein the protrusion is configured to engage the first engagement element when the ratchet mechanism is in the first configuration, to limit axial movement of the ratchet shuttle by the drive member, wherein the actuation member and the ratchet mechanism are arranged such that: a first actuation of the actuation member moves the ratchet mechanism from the first configuration to the second configuration to cause a first dose of the medicament to be dispensed, and a second actuation of the actuation member, subsequent to the first actuation, moves the ratchet mechanism from the second configuration to the third configuration to cause a second dose of the medicament to be dispensed; wherein the method comprises: actuating the actuation member of the medicament delivery device to dispense a first dose of the medicament; and subsequent to actuating the actuation member of the medicament delivery device to dispense the first dose of the medicament, actuating the actuation member of the medicament delivery device to dispense a second dose of medicament.