

## AUTO-INJECTOR WITH FILLING MEANS

### Field of the Invention

The present invention relates to an injection device for use with a vial.

### Background of the Invention

5 Subcutaneous drugs can be supplied to patients in a vial for home injection. The current method is for the patient to draw the drug from the vial into a syringe and perform a manual injection. The market is moving towards auto-injectors to carry out home injection. Auto-injectors which are manufactured and assembled including a pre-filled syringe of drug are known, for example from international patent application publication  
10 no. 2006/106295, which is incorporated herein by reference. There is currently no easy way for a patient to transfer a subcutaneous drug from a vial into an auto-injector.

### Summary of the Invention

The present invention aims to solve the aforementioned problems.

In a first aspect of the invention, there is provided an injection device comprising:

15 a housing adapted to receive a fluid container having a discharge nozzle and a dispensing piston moveable in the fluid container to expel the contents of the fluid container out of the discharge nozzle;

a drive adapted on activation to act on the fluid container to advance it from a retracted position in which the discharge nozzle is contained within the housing to an  
20 extended position in which the discharge nozzle extends from the housing and act on the dispensing piston to expel the contents of the fluid container out of the discharge nozzle;

characterised by:

a connector adapted to receive a vial containing fluid and connect it to the discharge nozzle; and

25 means to move the dispensing piston relative to the fluid container from a first position in which the dispensing piston is located in the fluid container adjacent the

discharge nozzle to a second position in which the dispensing piston has been drawn away from the discharge nozzle, thereby drawing fluid from the vial into the fluid container.

- 5 The provision of means to move the dispensing piston relative to the fluid container permits the syringe in the injection device to be filled from a standard vial which greatly facilitates home use of the injection device for drugs that are contained in vials.

In one embodiment of the present invention, the injection device comprises a drive sub-assembly including the drive and dispensing piston and a dispensing sub-assembly including the connector and fluid container,

wherein the dispensing piston is connected to the drive,

wherein the drive sub-assembly and dispensing sub-assembly are adapted to slide relative to each other,

- 15 wherein the drive sub-assembly and dispensing sub-assembly are arranged such that when they are pulled apart from each other, the dispensing piston moves from its first position into its second position thereby transferring fluid from the vial into the fluid container.

- 20 Preferably, the dispensing sub-assembly is adapted to slide, in part, inside the drive sub-assembly.

Preferably, the dispensing sub-assembly and drive sub-assembly are adapted to rotate relative to each other from an unlocked position in which the dispensing sub-assembly can slide relative to the drive sub-assembly to a locked position in which the dispensing sub-assembly cannot slide relative to the drive sub-assembly. In order to facilitate this, locking protrusions may be provided on one of the dispensing sub-assembly or drive sub-assembly and corresponding grooves are provided on the other.

- 30 In an alternative embodiment of the invention, the moving means comprises a slider located in the housing in communication with the dispensing piston. The slider may comprise a user-actuatable movement element which protrudes from the housing. The

slider may be in magnetic communication with the dispensing piston. Alternatively, the slider may be integrally connected to the dispensing piston.

The receiving means may be a removable cap located over the discharge nozzle on the injection device, wherein the cap has an open end which is adapted to receive the vial, wherein the removable cap is adapted such that removal of the cap from the housing detaches the vial from the discharge nozzle. The removable cap may comprise a removable cover element over the open end, wherein the removable cover element is adapted to be removed prior to insertion of a vial into the open end. Preferably, the removable cover element holds a shield which is located over the discharge nozzle when the removable cover element is in place on the removable cap and which becomes removed from the discharge nozzle when the removable cover element is removed from the removable cap.

On insertion of the vial into the connector, the discharge nozzle pierces a closure element of the vial to form a fluid pathway between the vial and the fluid container.

Preferably, the fluid container is a syringe and the discharge nozzle is a needle.

Preferably, the injection device comprises a release mechanism adapted on activation to release the drive to act on the dispensing piston to move the syringe to its extended position and eject fluid via the discharge nozzle.

In one embodiment of the invention, there is provided a retraction mechanism adapted to move the fluid container from its extended position to its retracted position after the contents of the fluid container has been expelled.

### **Brief Description of Drawings**

One or more embodiments of the present invention are described below with reference to the accompanying drawings, in which:-

Fig. 1 shows a perspective view of sub-assemblies of the injection device according to one embodiment of the present invention;

Fig. 2 shows an exploded view of components of the injection device according to embodiment of Fig. 1;

- 5 Figs. 3a to 3d show side cross-sectional views of an injection device according to Fig. 1; and

Figs. 4a to 4d show side cross-sectional views of an injection device according to an alternative embodiment of the invention.

#### **Detailed Description of the Drawings**

- 10 Figs. 1 and 2 show a delivery device 110 according to the present invention, having a delivery device housing 112 with a proximal end 110b and a distal end 110a. The distal end 110a of the housing 112 has an exit aperture 128, through which the end of a sleeve 119 can emerge.

- The delivery device 110 is assembled from two sub-assemblies as shown in Fig. 1. A  
15 delivery sub-assembly 210 comprises nose portion 102, a syringe carrier 150, an interchangeable release element 155, sleeve 119 and spring 126, as well as an end-cap 101. The nose portion 102 surrounds and supports the syringe carrier 150 and connects to the 101 cap by a screw and twist connection.

- A drive sub-assembly 220 comprises the housing 112 and drive elements and actuators  
20 of the injection device 110 as will be discussed below. Upon assembly of the two sub-assemblies 220, 210 to form the injection device 110, the drive assembly 220 is able to actuate the syringe 114 held by the delivery sub-assembly 210. After actuation, the two sub-assemblies can be separated and the drive elements and actuators of the drive assembly 220 reset for further use.

- 25 The housing 112 is adapted to receive a hypodermic syringe 114 of conventional type, including a syringe body 116 defining a reservoir and terminating at one end in a hypodermic needle 118 and at the other in a flange 120. The syringe body 116 is of

substantially constant diameter along the length of the reservoir, and is of significantly smaller diameter close to the end of the syringe 114 which terminates in the hypodermic needle. A drive coupling 134 acts through the bung of the syringe 114 to discharge the contents of the syringe 114 through the needle 118. This drive coupling 134 constrains a  
5 drug to be administered via a plunger 104 within the reservoir defined by syringe body and also permits the drug to be loaded into the syringe 114. Whilst the syringe 114 illustrated is of hypodermic type, this need not necessarily be so. Transcutaneous or ballistic dermal and subcutaneous syringes may also be used with the injection device of the present invention.

10 As illustrated, the syringe 114 is housed in the syringe carrier 150 within the delivery sub-assembly 210. The syringe carrier 150 has a proximal end 151 through which the needle 118 of the syringe protrudes. The return spring 126, via the return spring support 160 and the syringe carrier 150 biases the syringe 114 from an extended position in which the needle 118 extends from the aperture 128 in the housing 112 to a retracted  
15 position in which the needle 118 is contained within the housing 112.

The syringe carrier 150 comprises a sheath (not shown) into which the syringe 114 can be inserted from a distal end 170. The syringe 114 is provided with a boot 101a over the needle 118. If the syringe were to fail or break, the sheath, which surrounds the syringe 114 along its length, would contain the broken pieces of syringe and reduce the  
20 likelihood of them from escaping from the injection device 110.

The boot 101a protects the needle 118 and seals it against contamination prior to removal of the boot 101a. The boot 101a is gripped, after the syringe 118 has been inserted into delivery sub-assembly 210, by cap 101, which is removably located on the housing 112 over the exit aperture 128. The boot 101a is gripped in cap 101 by cover  
25 element 101b which is removable from the cap 101 so that the boot 101a is also removed, thereby exposing a port 101c, which is an opening formed in an open end of the cap 101.

The housing 112 of the drive assembly 220 also includes an actuator 214, and a drive which here takes the form of a compression drive spring 130. Drive from the drive  
30 spring 130 is transmitted via a multi-component drive to the piston of the syringe 114 to

advance the syringe 114 from its retracted position to its extended position and discharge its contents through the needle 118. The drive accomplishes this task by acting directly on the drug and the syringe 114. Static friction between the drive coupling 134 and the syringe body 116 initially ensures that they advance together, until the return spring 126  
5 bottoms out or the syringe body 116 meets some other obstruction (not shown) that retards its motion.

The multi-component drive between the drive spring 130 and the syringe 114 consists of three principal components. A drive sleeve 131 takes drive from the drive spring 130 and transmits it to a drive element 132. This in turn transmits drive to the drive coupling 134  
10 already mentioned.

The drive element 132 includes a user-actuatable syringe loading element 133 which engages with the drive coupling 134 internally via locking elements 133c and extends via a first arm 133a through the drive element 132. On assembly, in an unloaded position, a distal end 235 of the drive coupling 134 sits against a plunger 104 within the  
15 syringe 114 at its distal end adjacent the connection to the needle 118. The first arm 133a is connected at its proximal end to a second arm 133b which comprises a user-actuatable protrusion 133d. On assembly, the user-actuatable protrusion 133d extends out of the housing via slot 190. A further slot (not shown) on the proximal end of the housing 112 permits the first and second arms 133a, 133b to extend out of the housing  
20 112 when the syringe loading element 133 and plunger 104 is moved by sliding user-actuatable protrusion 133a proximally to a proximal position, adjacent the open end 114a of the syringe 114. In the loaded position, the drive element 132 becomes locked to drive coupling 134 via latching arms 132a, 134a on the drive element 132 and drive coupling 134. Thus, the drive coupling 134 can now move with the drive element 132  
25 and drive sleeve 131 on release of the drive spring 130. In an alternative embodiment of the invention, the syringe loading element 133 may be connected directly to the plunger through a bore in the first arm 133a and the drive coupling 134 may be in a proximal position at the open end 114a of the syringe 114. The syringe loading element 133 is then actuated to slide the plunger 104 to wards a proximal position at the open end 114a  
30 of the syringe 114 adjacent the syringe coupling 134.

The actuator 214, in the form of a trigger, is provided on the housing 112 remote from the exit aperture 128. The trigger, when operated, serves to decouple the drive sleeve 131 from the housing 112, allowing it to move relative to the housing 112 under the influence of the drive spring 130. The operation of the device is then as follows. The actuator 214 is prevented from being actuated by sliding sleeve 119 and sliding sleeve locking element 119a when the sliding sleeve 119 is in its most distal position extending out of the exit aperture 128. When the distal end of the sliding sleeve is placed against tissue or pushed into the exit aperture, the locking element 119a no longer acts on the actuator 214 and the actuator can be actuated.

10 The actuator is then depressed and the drive spring 130 is released. The drive spring 130 moves the drive sleeve 131, the drive sleeve 131 moves the drive element 132 and the drive element 132 moves the drive coupling 134. The drive coupling 134 moves and, by virtue of static friction and hydrostatic forces acting through the drug to be administered, moves the syringe body 114 against the action of the return spring 126. The syringe body 15 114 moves the syringe carrier 150, which in turn moves the return spring support 160 and compresses the return spring 126. The hypodermic needle 118 emerges from the exit aperture 128 of the housing 112. This continues until the return spring 126 bottoms out or the syringe body 116 meets some other obstruction (not shown) that retards its motion. Because the static friction between the drive coupling 134 and the syringe body 20 116 and the hydrostatic forces acting through the drug to be administered are not sufficient to resist the full drive force developed by the drive spring 130, at this point the drive coupling 134 begins to move within the syringe body 116 and the drug begins to be discharged. Dynamic friction between the drive coupling 134 and the syringe body 116 and hydrostatic and hydrodynamic forces now acting through the drug to be administered are, however, sufficient to retain the return spring 126 in its compressed state, so the hypodermic needle 118 remains extended.

Before the drive coupling 134 reaches the end of its travel within the syringe body 116, so before the contents of the syringe have fully discharged, flexible latch arms 134b linking the first and drive couplings 132, 134 reach an interchangeable release element 30 155 connected to the distal end of the syringe carrier 150.

The interchangeable release element 155 is essentially a constriction which moves the flexible latch arms 132b to a position so that they no longer couple the drive element 132 to the drive coupling 134. Once this happens, the drive element 132 acts no longer on the drive coupling 134, allowing the drive element 132 to move relative to the drive coupling 134. Consequently, the drive coupling 134 continues to move within the syringe body 116 and the drug continues to be discharged. Thus, the return spring 126 remains compressed and the hypodermic needle remains extended.

After a time, the drive coupling 134 completes its travel within the syringe body 116 and can go no further. At this point, the contents of the syringe 114 are completely discharged and the force exerted by the drive spring 130 acts to retain the drive coupling 134 in its terminal position, allowing the drive element 132 to continue its movement.

Flexible latch arms linking the drive sleeve 131 with the drive element 132 reach another constriction within the housing 112. The constriction moves the flexible latch arms so that they no longer couple the drive sleeve 131 to the drive element 132. Once this happens, the drive sleeve 131 acts no longer on the drive element 132, allowing them to move relative each other. At this point, the forces developed by the drive spring 130 are no longer being transmitted to the syringe 114. The only force acting on the syringe will be the return force from the return spring 126 which acts on the end of the syringe 114 nearest to the needle 118 via the return spring support 160 and the syringe carrier 150. Consequently, the syringe is returned to its retracted position and the injection cycle is complete.

Figs. 3a to 3d show one embodiment of the injection device 110 and the steps by which it is loaded with fluid from a vial 300 prior to injection. The vial 300 is of standard size and comprises a closure element 301 which seals the vial. The closure element 301 may be in the form of a flexible membrane which can be pierced by the needle 118. The port 101c in the cap 101 is sized and dimensioned to receive the vial 300 and support it whilst fluid is extracted from the vial into syringe 114. The process for doing this is as follows.

As shown in Fig. 3b, the closure element 101b is removed from the cap 101 whilst the cap 101 remains in place on the housing 112. This removes the boot 101a from the needle 118 and opens the port 101c, in which the needle 118 is exposed.

The vial 300 is inserted into the port 101c end first, i.e. the end which includes the closure element 301. As the vial 300 is inserted, the needle pierces the closure element 301 and extends into the vial 300 so that its end point resides in the fluid contained within the vial 300. Preferably, the injection device 110 should now be positioned so  
5 that its longitudinal axis extends vertically with the vial 300 located nearest the ground. Gravity acts on the fluid in the vial 300 to keep it in the bottom of the vial, so that the fluid can be extracted.

The user can now operate the syringe loading element 133 by sliding the protrusion 133d towards the proximal end of the injection device 110. This causes the plunger 104 in the  
10 syringe 114 to move from its unloaded position towards the proximal end of the syringe 114 into its loaded position and extract fluid from the vial 300 into the syringe 114 via a reduction of pressure in the syringe 114. When the syringe loading element 133 has reached its loaded position, i.e. at the most proximal end of the slot 190, the syringe 114 has been loaded with fluid from the vial 300. The vial 300 can now be removed from  
15 the injection device 110 by removing the cap 101 so that the injection device 110 is ready for use, by placing the distal end of the sliding 119 sleeve against tissue and activating the actuator 214.

Figs. 4a to 4d show an alternative embodiment of the injection device 110 and the steps by which it is loaded with fluid from a vial 400 prior to injection. The structure of the  
20 injection device 110 of this alternative embodiment is the same as for the embodiment depicted in Figs 1 and 2, except for the differences explained below. As in the embodiment of Figs. 3a to 3d, the vial 400 is of standard size and comprises a closure element 405 which seals the vial 400. The closure element 405 may be in the form of a flexible membrane which can be pierced by the needle 118. In this alternative  
25 embodiment, the cap 401 of the delivery sub-assembly 210, comprises a cover element 401b and flange 401d at its distal end. The cap 401 is also connected to nose portion 402 of the delivery sub-assembly 210 which is slidable and rotatable into and out of the housing 112 between an unloaded and loaded position. In its extended loaded position, the nose portion 402 can be rotated to lock its position relative to the housing 112. As in  
30 the embodiment described in Figs. 1 and 2, the nose portion 402 supports the syringe 114 which moves with the syringe portion relative to the drive coupling 134, which in

this alternative embodiment, is fixed to the drive element 132. In this alternative embodiment, there is no syringe loading element. A port 401c in the cap 101 is sized and dimensioned to receive the vial 400 and support it whilst fluid is extracted from the vial into syringe 114. The process for doing this is as follows.

- 5 As shown in Fig. 4b, the closure element 401b is removed from the cap 401 whilst the cap 401 remains in place on the housing 112. This removes the boot 101a from the needle 118 and opens the port 401c, in which the needle 118 is exposed.

The vial 400 is inserted into the port 401c end first, i.e. the end which includes the closure element 401. As the vial 400 is inserted, the needle 118 pierces the closure  
10 element 401 and extends into the vial 400 so that its end point resides in the fluid contained within the vial 400. Preferably, the injection device 110 should now be positioned so that its longitudinal axis extends vertically with the vial 300 located nearest the ground. Gravity acts on the fluid in the vial 400 to keep it in the bottom of the vial, so that the fluid can be extracted.

- 15 The user can now slide the delivery sub-assembly 210 relative to the drive sub-assembly 220 by, for example, pulling on the flange 401d to cause the cap 401 and nose portion 402, including the syringe 114, to extend away from the distal end of the drive sub-assembly 220. This causes the plunger 104, held by the drive coupling 134, in the syringe 114 to move from its unloaded position towards the proximal open end 114a of  
20 the syringe 114 into its loaded position and extract fluid from the vial 400 into the syringe 114 via a reduction of pressure in the syringe 114. When the delivery sub-assembly 210 is fully extended from the drive sub-assembly 220, the cap 401 and nose portion 402 can be rotated to lock and prevent further longitudinal movement of the delivery sub-assembly 210 relative to the drive sub-assembly 220. The syringe 114 has  
25 now been loaded with fluid from the vial 400. The vial 400 can now be removed from the injection device 110 by removing the cap 101, for example by further rotation, so that the injection device 110 is ready for use, by placing the distal end of the sliding 119 sleeve against tissue and activating the actuator 214.

It will of course be understood that the present invention has been described above purely by way of example and modifications of detail can be made within the scope of the invention.

## **Claims**

1. An injection device comprising:
  - a housing adapted to receive a fluid container having a discharge nozzle and a
  - 5 dispensing piston moveable in the fluid container to expel the contents of the fluid container out of the discharge nozzle;
  - a drive adapted on activation to act on the fluid container to advance it from a retracted position in which the discharge nozzle is contained within the housing to an extended position in which the discharge nozzle extends from the housing and act on the
  - 10 dispensing piston to expel the contents of the fluid container out of the discharge nozzle;
  - characterised by:
    - a connector adapted to receive a vial containing fluid and connect it to the discharge nozzle, wherein the receiving means is a removable cap located over the discharge nozzle on the injection device, wherein the cap has an open end which is
    - 15 adapted to receive the vial, wherein the removable cap is adapted such that removal of the cap from the housing detaches the vial from the discharge nozzle; and
    - means to move the dispensing piston relative to the fluid container from a first position in which the dispensing piston is located in the fluid container adjacent the discharge nozzle to a second position in which the dispensing piston has been drawn
    - 20 away from the discharge nozzle, thereby drawing fluid from the vial into the fluid container.
2. The injection device of claim 1, comprising a drive sub-assembly including the drive and dispensing piston and a dispensing sub-assembly including the connector and
- 25 fluid container,
  - wherein the dispensing piston is connected to the drive,
  - wherein the drive sub-assembly and dispensing sub-assembly are adapted to slide relative to each other,

wherein the drive sub-assembly and dispensing sub-assembly are arranged such that when they are pulled apart from each other, the dispensing piston moves from its first position into its second position thereby transferring fluid from the vial into the fluid container.

5

3. The injection device of claim 2, wherein the dispensing sub-assembly is adapted to slide, in part, inside the drive sub-assembly.

4. The injection device of claim 2 or claim 3, wherein the dispensing sub-assembly  
10 and drive sub-assembly are adapted to rotate relative to each other from an unlocked position in which the dispensing sub-assembly can slide relative to the drive sub-assembly to a locked position in which the dispensing sub-assembly cannot slide relative to the dispensing sub-assembly.

15 5. The injection device of claim 1, wherein the moving means comprises a slider located in the housing in communication with the dispensing piston.

6. The injection device of claim 5, wherein the slider comprises a user-actuatable movement element which protrudes from the housing.

20

7. The injection device of claim 5 or claim 6, wherein the slider is in magnetic communication with the dispensing piston.

8. The injection device of claim 5 or claim 6, wherein the slider is integrally  
25 connected to the dispensing piston.

9. The injection device of claim 1, wherein the removable cap comprises a removable cover element over the open end, wherein the removable cover element is adapted to be removed prior to insertion of a vial into the open end.
- 5 10. The injection device of claim 9 wherein the removable cover element holds a shield which is located over the discharge nozzle when the removable cover element is in place on the removable cap and which removed from the discharge nozzle when the removable cover element is removed from the removable cap.
- 10 11. The device of claim any one of the preceding claims, wherein, on insertion of the vial into the connector, the discharge nozzle pierces a closure element of the vial to form a fluid pathway between the vial and the fluid container.
12. The injection device of any one of the preceding claims, wherein the fluid  
15 container is a syringe and the discharge nozzle is a needle.
13. The injection device of any one of the preceding claims, comprising a release mechanism adapted on activation to release the drive to act on the dispensing piston to move the syringe to its extended position and eject fluid via the discharge nozzle.
- 20 14. The injection device of any one of the preceding claims, comprising a retraction mechanism adapted to move the fluid container from its extended position to its retracted position after the contents of the fluid container has been expelled.