

Housing and apparatus for storing a medical container

The present invention relates to a housing for receiving a medical container for example a multidose vial containing a pharmaceutical product, such as a vaccine. The housing is in particular capable of maintaining the temperature of the medical container within a predetermined range during the time needed for withdrawing all the doses of product contained in the vial with injection devices intended to be further used for dispensing said doses to various patients. The invention also relates to an assembly comprising such a housing with the medical container lodged therein, and to an apparatus for storing and transporting such assemblies.

In this application, the distal end of a component or apparatus must be understood as meaning the end furthest from the hand of the user and the proximal end must be understood as meaning the end closest to the hand of the user, with reference to the injection device intended to be used with said component or apparatus. As such, in this application, the distal direction must be understood as the direction of injection with reference to the injection device, and the proximal direction is the opposite direction, i.e. the direction of the transfer of the product from the vial to the injection device.

One of the ways to improve health is to immunize entire populations with vaccines against a number of diseases. To date, injection administration is the most common method of administering vaccines.

Each year, numerous drugs, for example vaccines, need to be prepared throughout the world by healthcare institutions. Many vaccine compositions are usually not stable at room temperatures and they must be stored at rather specific cold temperatures. Indeed, due to their biological nature, vaccines are complex to handle and to store. Vaccines are usually temperature sensitive and typically need to be maintained and stored at all time between 2 and 8 degrees Celsius (°C). Some vaccines will be more sensitive to heat exposure and others will be sensitive to freezing. Therefore, maintaining and monitoring the appropriate temperature during the storage and the handling of vaccines is a critical issue in order to sustain their efficacy. Overexposure to heat as well as overcooling may result in the destruction of the biological elements of the vaccines. Use of vaccines not stored in appropriate conditions may lead to not effective vaccination of the populations against diseases and may lead to expensive campaigns with limited results.

Furthermore, it is critical that the cold chain be not interrupted from production of the drug at a pharmaceutical company to its administration to the patient.

From a supply chain perspective, the most efficient vaccine packaging is the multidose container, that is to say, containers that may contain up to 10 or 20 doses of vaccine, one dose being intended for one patient. Nevertheless, it may happen that a multidose container, such as for example a 10-dose container, is opened and that only three doses are used, for vaccinating three patients only, the rest of the container being wasted because not intended to be administered in a sufficiently short time after opening of the container in order to guaranty the vaccine or drug sterility and its continuous handling at controlled temperatures.

Vaccination campaigns can therefore be made difficult in regions where there is limited or potentially no supply of energy to power cooling equipment such as a refrigerator. As a result, a significant proportion of vaccines may be wasted by the time they reach their target. This has an unacceptable cost to the health organizations in charge of immunization campaigns. In addition, it may happen that in case of vaccination campaigns, or pandemic, hundreds of patients need to be vaccinated in a very short time, in locations where it is difficult to maintain good hygienic conditions such as remote locations which are far from towns and from hospital facilities.

Therefore, it would be desirable to provide a device and/or a system that would maintain the temperature of a multidose vial in the good temperature range at least during the time that is needed for a user for withdrawing the multiple doses contained in the vial, and administering these doses to various patients.

An aspect of the present invention is a housing for receiving a medical container having a collar closed by a septum, said housing comprising at least a wall shaped and dimensioned so as to substantially surround said medical container while leaving free access to at least a portion of said septum, said housing further comprising a fixation system for maintaining said medical container lodged within said housing, said wall being made of an insulating material. This insulating material allows the medical container to be maintained at an appropriate temperature range. This insulating material also avoids or limits the warming of the medical container when the medical container is exposed to higher temperatures.

The housing of the invention is intended to receive a medical container, for example a conventional vial for storing pharmaceutical products, such as multidose vials for vaccines. Such a vial 1 is shown on Figures 1A-1C and generally comprises a tubular barrel 2 having a longitudinal axis A, closed at an end and having a collar 3 at the opposite end, said collar 3 being closed by a septum 4. Usually, the septum 4 is fixedly attached to the collar 3 of the vial 1 by a peripheral band 5, said peripheral band 5 leaving a part of the septum 4, herein called outer surface 4a of the septum, directly facing the outside of the vial 1, namely the outside environment. The septum 4 is usually made of a material impermeable to gas and liquid and it seals hermetically the content of the vial 1. The septum 4 is also pierceable by the needle of an injection device intended to be filled with the product contained in the vial, said septum 4 being accessible to said needle via its outer surface 4a.

The housing of the invention, equipped with a medical container such as a multidose vial received therein, is further intended to be stored in a removable way inside an apparatus comprising a cold storage accumulator. The cold storage accumulator transfers some of its cooling capacity to the wall of the housing, thereby providing said housing with its own and independent cooling capacity. As such, when the housing of the invention, in which is lodged a medical container such as a multidose vial, is retrieved from the apparatus, it maintains the temperature of the medical container at a predetermined range, for example between 2 and 8°C, at least during a certain time.

The housing of the invention allows maintaining the temperature inside the medical container at a predetermined range optimal for the good and safe storage of the product, such as a vaccine, contained therein.

In addition, because the housing of the invention is specific to one medical container and allows the medical container to be removed from the apparatus on its own, other medical containers which may be stored in the apparatus are not affected by the ambient temperature while the user withdraws multiple doses from the medical container in use.

In embodiments, said wall further includes a material capable of accumulating cold. Such embodiments allow storing a great amount of cooling capacity inside the housing intended to receive or receiving the medical container and therefore prevent heat transfer to the medical container. The maintaining of the appropriate temperature conditions is therefore excellent.

In embodiments, said wall comprises a plurality of insulating material layers. For example, the wall may be formed of two or more layers of insulating material. In embodiments, at least two adjacent insulating material layers are separated by a layer of air or vacuum. For example, all adjacent
5 insulating material layers are separated by a layer of air or vacuum, and the wall is formed of a succession of insulating material layers and air layers. The maintaining of the appropriate temperature conditions is therefore improved.

In embodiments, the fixation system is selected from friction means, snap-fitting means, and combinations thereof.

10 In embodiments, said wall comprises an opening for engagement of the medical container inside said housing. Such an opening may also allow a user to see the inside of the medical container once a housing is retrieved from the apparatus so as to check its contents before withdrawing a dose of product. For example, the opening may be a window closed by a transparent door
15 connected to the wall by hinges.

Another aspect of the invention is an assembly comprising a housing as described above and a medical container having a collar closed by a septum, wherein said medical container is received within said housing.

In embodiments, the assembly further comprises an adaptor
20 coupled on one hand to the collar of said medical container, and on the other hand to the fixation system of said housing. For example, the adaptor may be removably coupled to the housing and/or removably coupled to the collar of the medical container. For example, the fixation system may comprise snap-fitting means for coupling said adaptor to said housing.

25 In embodiments, said medical container being filled with a plurality of doses of product to be withdrawn therefrom with an injection device, said adaptor comprises a counting system for indicating how many doses of product have been withdrawn.

In embodiments, the assembly further comprises a triggering
30 system, said medical container being in one of an active or passive state with respect to said triggering system, said triggering system preventing access to said septum when said medical container is in said passive state, said triggering system allowing free access to said septum when said medical container is in said active state.

35 For example, the triggering system may consist in a collapsible leg having an end fixed to the housing or to the adaptor, and a mobile end

preventing access to the septum before any withdrawal of product from the medical container, said mobile end being collapsible by the user in order to free access to the septum at the time of proceeding to the first withdrawal of dose of product.

5 In embodiments, said triggering system is configured so that said medical container is moved from its passive state to its active state by pressure exerted on said medical container by a user. For example, the triggering system comprises a first attaching member and a second attaching member axially spaced from each other, said medical container being successively
10 engageable with the first attaching member and with the second attaching member under pressure exerted by a user, said septum being not reachable by the needle of an injection device when said medical container is engaged in said first attaching member, and said septum being reachable by the needle of an injection device when said medical container is engaged in said second
15 attaching member.

 In embodiments, the triggering system may be connected to, or part of, the counting system.

 In embodiments, the counting system may include a blocking member for preventing access to the septum by the needle of an injection
20 device when a predetermined number of doses of product have been withdrawn from the medical container.

 In embodiments, the assembly may comprise a time indicator for monitoring time elapsed from withdrawal of a first dose of product from the medical container. The time indicator may be activated manually by the user.
25 Alternatively, the time indicator may be activated automatically when the first dose of product is withdrawn from the medical container, for example by the triggering system, when the medical container goes from its passive state to its active state.

 In embodiments, the time indicator further comprises a locking
30 member for preventing access to the septum by the needle of an injection device when a predetermined time has elapsed since withdrawal of a first dose of product.

 In embodiments, the assembly further comprises an activation member for operating the counting system automatically, said activation
35 member being triggered by pressure exerted by a part of an injection device used for withdrawing a dose of product from the medical container.

Another aspect of the invention is an apparatus for storing at least one housing or assembly as described above, comprising an enclosed storage chamber comprising a cold storage accumulator, the cold storage accumulator including a series of openings receiving a series of housings or assemblies as described above.

In embodiments, the cold storage accumulator further comprises a recess for storing auxiliary medical recipients.

In embodiments, the auxiliary medical recipients contain lyophilisate usable in cooperation with a product contained in the medical container for reconstitution of a drug.

In embodiments, the apparatus further comprises an activation system for automatically activating the triggering system of an assembly when said assembly is removed from said apparatus.

In embodiments, the apparatus further comprises a blocking system for preventing the removal of an assembly from the apparatus when a predetermined number of doses of product have been withdrawn from the medical container received in said assembly.

In embodiments, said time indicating system is activated by the first removal of said assembly from said apparatus.

In embodiments, said time indicating system comprises a locking system for preventing the removal of an assembly from the apparatus when a predetermined time has elapsed since first removal of said assembly from said apparatus.

The apparatus according to the invention is appropriate to be used in remote areas as it can contain different medical containers having different contents with the guaranty that the drugs will be preserved in the good conditions in term of contamination, sterility but also in term of temperature.

The present invention will now be described in greater detail based on the following description and the appended drawings in which:

Figures 1A-1C are respectively a perspective view, a partial side view and a partial cross section view of a medical container of the assembly of the invention,

Figures 2A-2C are respectively a cross section view, a perspective view from the top and a perspective view from the bottom of the housing of the invention,

Figure 3 is a perspective view from the bottom of an adaptor to be coupled on a medical container of the assembly of the invention,

Figure 4 is cross section view of the adaptor of Figure 3 coupled on a vial of Figures 1A-1C,

5 Figure 5 is an exploded perspective view of a variant of the adaptor of Figure 3 comprising a manual counting system,

Figure 6 is a top view of the counting system of the adaptor of Figure 5,

10 Figures 7A and 7B are perspective views respectively from the top and from the bottom of the assembled adaptor of Figure 5,

Figures 8A and 8B are respectively a cross section view and a perspective view from the top of the adaptor of Figure 5 coupled to a vial of Figures 1A-1C filled with a product,

15 Figures 9A and 9B are respectively a cross section view and a perspective view from the bottom of an assembly of the invention, comprising a housing of the invention receiving the medical container of Figures 8A and 8B,

Figure 10 is a perspective view from the top of an apparatus of the invention, intended to receive a plurality of assemblies of Figures 9A-9B,

20 Figure 11 is a cross section view of the apparatus of Figure 10 once the assemblies are received therein,

Figure 12 is a perspective view from the top of the apparatus of Figure 12 intended to receive auxiliary medical recipients,

Figure 13 is a cross section view of the apparatus of figure 12 once the auxiliary medical recipients are received therein,

25 Figure 14 is an exploded perspective view of a variant of the adaptor of Figure 5 in which the counting system is automatic,

Figure 15 is a partial side view of the adaptor of Figure 14 mounted on a vial,

30 Figure 16 is a cross section view of the adaptor of Figure 14 mounted on a vial during a withdrawal step.

For purposes of the description hereinafter, the terms "upper", "lower", "right", "left", "vertical", "horizontal", "top", "bottom", "lateral", "longitudinal", and derivatives thereof shall relate to the invention as it is oriented in the drawing figures.

35 With reference to Figures 2A-C is shown a housing 100 in accordance with an embodiment of the invention. The housing is shaped and

dimensioned so as to receive a medical container such as a conventional vial for storing vaccines or a cartridge. For example, the housing 100 is intended to receive a medical container such as a vial 1 of Figures 1A-1C. The housing 100 comprises a wall 101 shaped and dimensioned so as to substantially surround the vial 1 while leaving free access to at least a portion of the outer surface 4a of the septum 4 (see for example Figure 9A). On the example shown, the wall 101 of the housing 100 is also provided with an opening under the form of a window 102 for engagement and loading of the vial 1 inside the housing 100. As such, on Figures 2A-C, the wall 101 therefore defines a partially cylindrical cavity 103 for receiving the vial 1. In an embodiment not shown, a door, such as a transparent door connected to the wall by hinges, could be provided in order to close the window 102.

In embodiments not shown, the opening could be under the form of an end part of the housing that could be connected to the rest of the housing by screwing or snapping and that could be temporarily disconnected therefrom for allowing the loading of the medical container.

In embodiments not shown, the wall of the housing could define a cavity of any shape, corresponding to the shape of the vial intended to be received therein, as long as the wall substantially surrounds said vial.

The wall 101 is made of an insulating material. For example, the wall 101 may include one or more layers of insulating material. If at least two insulating material layers are present to form the wall 101, a layer of air or vacuum may be present between the two insulating material layers : the capacity of the wall 101 to maintain the cold inside the housing 100 may therefore be enhanced.

The insulating material may be selected from elastomeric foams, expanded rubbers and polyolefins, cellulose, cotton, poly-(ethyleneterephtalate), polyester, fiber glass, mica, metallic foils, EVA, ceramic, epoxy, wood, polyurethane, polyisocyanurate, and combinations thereof.

Additionally, the wall may further include a material capable of accumulating cold.

On the example shown on figures 2A-C, the wall 101 shows a portion 101a of greater thickness : as shown later in the description, this portion of greater thickness is intended to face the bottom of the vial 1. On the example shown, this portion 101a has a thickness corresponding to more than twice the

length of the cavity 103. This portion 101a is solid : such a solid portion of greater thickness made of the insulating material and for example of material capable of accumulating cold allows to store a high amount of cooling capacity and to maintain the temperature of the vial 1, once received inside the housing, at a predetermined range, between 2 and 8°C for example.

In an embodiment not shown, the portion 101a forms a recess in which ice packs can be introduced to maintain as much as possible the temperature of the medical container received in the housing 100 between 2 and 8 °C.

On the example shown, the housing 100 therefore shows a global shape of a solid cylinder provided at one end with a cavity 103 for receiving the vial 1 and at the other end with a grasping projection 104 for a user to hold the housing 100. As described above, the cavity 103 may be either open or closed, depending on the how the loading of the medical container is intended to be completed.

In embodiments not shown, the portion of the wall of greater thickness could be intended to face a lateral side of the vial 1, and could therefore extend in a radial direction with respect to the partially cylindrical cavity.

On the example shown on Figures 2A-C, the cavity 103 is provided at its distal end 103a with a transversal annular wall 105. As shown later in the description, this transversal annular wall 105 is intended to provide a distal abutment for the vial 1 lodged within the cavity 103.

The housing 100 is further provided on the inner face of the cavity 103 with an annular ridge 106. As shown later in the description, this annular ridge 106 is intended to cooperate with the vial 1 or with an adaptor coupled to the vial 1 so as to form a fixation system for maintaining the vial 1 fixedly lodged within the housing 100.

In embodiments, an adaptor, intended to be coupled on one hand to the collar of the medical container, such as the vial 1, and on the other hand to the fixation system of the housing 100, is provided. The adaptor may be coupled to the housing 100 in a permanent way and therefore be intended to receive the medical container. Alternatively, the adaptor may be coupled to the housing 100 in a removable way. In embodiments, the adaptor may be coupled to the medical container in a permanent way, and therefore be intended to be loaded and mounted on the housing 100 together with the medical container.

Alternatively, the adaptor may be coupled to the medical container in a removable way.

With reference to Figure 3, is shown an adaptor 10 to be coupled onto the collar 3 of the vial 1. The adaptor 10 is intended to provide surfaces capable of cooperating with the annular ridge 106 for forming a fixation system for maintaining the vial lodged within the housing 100. The adaptor 10 may also serve for protecting the septum 4 of the vial 1.

The adaptor 10 comprises a gripping member 20 intended to secure the adaptor onto the vial 1, and an elastomeric piece 30 which is pierceable by the needle of an injection device (not shown). The gripping member 20 comprises a U-shaped body 21, having a partially tubular wall 22 showing a height suitable for surrounding the collar 3 of the vial 1, with two free ends 22a corresponding to the ends of the branches of the U, the U-shaped body 21 therefore forming a clipping member. Each free end 22a is further provided with a distal front projection forming a radial rim 27. In its circular portion, the partially tubular wall 22 is provided on its inner surface with a forward projection 29.

The U-shaped body 21 is further provided at its proximal end with an inner annular rim 21a, forming a central hole in which is lodged the elastomeric piece 30.

On the example shown, the adaptor 10 further comprises a cap 40 surrounding the gripping member 20 and coupled to the gripping member 20 by means of pegs 46 engaged in recesses provided on the outer surface of the partially tubular wall 22. The cap 40 comprises a proximal transversal wall 41 and tubular wall 42 extending distally from the proximal transversal wall 41. The proximal transversal wall 41 is also provided with a central hole 43 receiving the elastomeric piece 30. This elastomeric piece 30 being pierceable by the needle of an injection device, it allows access to the septum 4 and then to the inside of the vial 1 when a user wishes to withdraw a dose of product from the vial 1, once the adaptor 10 is coupled onto the collar 3 of the vial 1. The elastomeric piece 30 may also protect the septum 4 from the environment.

The pierceable elastomeric piece 30 may be made of a material impermeable to gas and liquid capable of flexing under pressure. For example, the elastomeric piece has a thickness ranging from 1 to 8 mm, preferably from 2 to 4 mm. The elastomeric piece may show a hardness ranging from 10 to 100 Shore A, preferably from 40 to 70 Shore A, measured according to DIN 53505.

Suitable materials for the pierceable elastomeric piece 30 of the adaptor include natural rubber, acrylate-butadiene rubber, cis-polybutadiene, chloro or bromobutyl rubber, chlorinated polyethylene elastomers, polyalkylene oxide polymers, ethylene vinyl acetate, fluorosilicone rubbers, hexafluoropropylene-vinylidene fluoride-tetrafluoroethylene terpolymers, butyl rubbers, polyisobutene, synthetic polyisoprene rubber, silicone rubbers, styrene-butadiene rubbers, tetrafluoroethylene propylene copolymers, thermoplastic-copolyesters, thermo-plastic elastomers, or the like or a combination thereof.

With reference to Figure 4 is shown the adaptor 10 once coupled to the collar 3 of the vial 1. To reach this position, the gripping member 20 has been clipped onto the collar 3 : the radial rims 27 and forward projection 29 are engaged around the collar 3 of the vial 1 and maintain the adaptor 10 coupled to the vial 1.

The vial 1 of Figure 4 with the adaptor 10 coupled thereto may then be lodged within the cavity 103 of the housing 100 of Figure 2A-C by introducing the vial 1 through the window 102 and snap-fitting the adaptor 10, and in particular the cap 40, between the annular ridge 106 and the transversal annular wall 105. Thanks to the central hole defined by the transversal annular wall 105, the elastomeric piece 30 and the septum 4 remain accessible to the needle of an injection device (not shown). The inside of the vial 1, and in particular the product contained therein, is therefore accessible by the needle of an injection device.

In embodiments, the vial as described in Figures 1A-1C may be partially or totally covered by an insulating sleeve. This insulating sleeve can cover the vial itself but also the vial after it has been connected to the adaptor. It may be made of flexible insulation materials such as elastomeric foams, expanded rubbers and polyolefins, cellulose, cotton, poly-(ethyleneterephthalate), polyester, fiber glass, mica, metallic foils, EVA and combinations thereof, but also of non-flexible materials such as ceramic, epoxy, wood, polyurethane, polyisocyanurate and combination thereof. This individual insulating sleeve can be placed around the vial for maintaining as much as possible the contents of the vial at the desired temperature. Indeed the use of this insulating sleeve allows an improved insulation of the medical container by maintaining the medical container at a temperature in the optimal range for storage of a drug or a vaccine, for example 2 to 8 °C.

As described previously, the assembly of the present invention may further comprise a counting system for indicating how many doses of product have been withdrawn or are remaining in the medical container.

With reference to Figures 5-7B is shown an adaptor 310 further comprising a counting system under the form of a manual dose counter 91.

The references designating the same elements as in Figures 3-4 have been maintained, augmented of 300.

With reference to Figures 5-7B, the cap 340 comprises a tubular wall 342 closed at its proximal end by a transversal wall 341 provided with a central hole 343. The tubular wall 342 is provided with an opening 344 on a part of its circumference and on its whole height, herein called "front part" of the cap 340, the opening 344 comprising a transversal bridge 347 defining a proximal window 347a. The proximal face of the transversal wall 341 is provided with an opening 341b (see Figure 7A) radially spaced with respect to the center of the transversal wall 341. The distal face of the transversal wall 341 is provided with a distally extending collar 348 surrounding the central hole 343. In the distal region of the outer wall of the distally extending collar 348 are located two opposite outer ears 348a, only one of them being visible on Figure 5. The distal face of the transversal wall 341 is further provided with a plurality of circumferentially distributed recesses 349 located around the distally extending collar 348.

The gripping member 320 comprises a partially tubular wall 322 provided with radial rims 327 and forward projection 329 for engagement around the collar 3 of the vial 1 (see Figure 8A).

With reference to Figure 6, the dose counter 91 is made of a flat cylinder 92 provided with a plurality of circumferentially distributed peripheral projections 93 extending radially outwardly. The flat cylinder 92 is further provided with a central hole 94 dimensioned and shaped so as to fit around the distally extending collar 348 of the distal face of the transversal wall 341 of the cap 340, and so as to be snap-fitted thereon after overcoming the outer ears 348a of said distally extending collar 348. The flat cylinder 92 is snap-fitted on the collar 348 so that it is able to rotate with respect to said collar 348.

Still with reference to Figure 6, the proximal face of the flat cylinder 92 is further provided with two proximal pegs 95 located around the central hole 94. As will be shown later, these two proximal pegs 95 are intended to cooperate with the recesses 349 of the distal face of the transversal wall 341 of

the cap 340. The proximal face of the flat cylinder 92 is further provided with a plurality of circumferentially distributed information data 96, such as digits from "0" to "10" on the example shown.

When the adaptor 310 is assembled, as shown on Figures 7A and 7B, the flat cylinder 92 is snap-fitted onto the distally extending collar 348 of the distal face 341 of the cap 340 and it is therefore received within said cap 340 with a part of it protruding outside via the window 347a. The flat cylinder 92 is capable of rotating with respect to the collar 348, therefore with respect to transversal wall 341. Anyway, before use, one of the information data, for example digit "0" faces the opening 341b of the transversal wall 341 and it is therefore visible by the user. In addition, in order to temporarily maintain the flat cylinder 92 in this position with respect to the transversal wall 341, the proximal pegs 95 are each engaged in one of the plurality of circumferentially distributed recesses 349 located around the distally extending collar 348.

On Figures 8A-8B is shown the adaptor 310 of Figures 5-7B coupled onto the collar 3 of a vial 1 filled with doses of a product 6. As shown on Figure 8A, the radial rims 327 and forward projection 329 of the gripping member 20 of the adaptor are engaged around the collar 3 of the vial 1.

On Figures 9A-B, is shown the vial 1 of Figures 8A-B, coupled with the adaptor 310 of Figure 5, once received in the housing 100 of Figures 2A-C, thereby forming an assembly 110. As shown on Figures 9A-B, the vial 1 and its adaptor 310 have been introduced in the cavity 103 via the window 102 and the cap 340 is clipped between the annular ridge 106 and the transversal annular wall 105.

Because of the insulating capacity, and for example the cooling capacity, of the housing 100, the vial 1 received within the cavity 103 is maintained at a predetermined temperature range, preferably between 2 and 8°C, for example if a vaccine is contained in the vial 1. In addition, as shown on figures 9A-B, access to the product 6 of the vial 1 is possible for the needle of an injection device (not shown) via the hole 343, and then via piercing the elastomeric piece 30 and the septum 4.

Therefore, a user may use the assembly 110 of the invention, as shown for example on Figures 9A-B, in order to withdraw several doses of product 6 from the vial 1, in an environment such as ambient air, having a temperature of around 20°C or more, without fearing that the temperature

inside the vial 1 moves out of the range of 2-8°C necessary for the good storage conditions of the product 6, for example a vaccine.

In addition, with the vial 1 and its adaptor 310 lodged within the cavity 103 of the housing 100 as shown on Figures 9A-B, the user may use the dose counter 91 in order to determine how many doses of product 6 have been already withdrawn or on the contrary how many of such doses are remaining inside the vial 1.

In this view, and with reference to Figures 5-7B and 9A-B, before withdrawing a first dose of product 6 from the vial 1, the user rotates the flat cylinder 92, for example manually by grasping one of the plurality of circumferentially distributed peripheral projections 93 extending radially outwardly, for example in the direction of the arrow 341c shown on Figure 7A. With this rotational movement, the proximal pegs 95 overcome the recesses 349 in which they were engaged, and become engaged in adjacent recesses 349, in which position the digit "1" now appears through opening 341b of the proximal face of the transversal wall 341.

The user may repeat this operation for each dose of product 6 he withdraws from the vial 1, until digit "10" appears through opening 341b, thereby indicating that the vial 1 is empty and may be disposed.

The flat cylinder 92 therefore forms a dose counter for counting how many doses of product 6 have already been withdrawn from, or remain in, the medical container.

The assembly 110 of the invention allows withdrawing multiple doses from a vial 1 in good temperature conditions during the time necessary for withdrawing and further dispensing said multiple doses. Indeed, with the assembly 110 of the invention, the temperature inside the vial 1 is kept at an optimal range, for example 2 to 8°C, for optimal storage of the product, for example vaccine, contained therein, during the time needed for withdrawing the number of doses of product contained in the vial 1.

The user may repeat the piercing step with the needle of a new empty syringe until all the doses contained in the vial are removed. The adaptor acts as a protection of the septum of the vial. Using an adaptor minimizes the risk of contamination for the following dose withdrawals.

In embodiments not shown, the assembly further comprises a triggering system, the vial being in one of an active or passive state with respect to said triggering system, said triggering system preventing access to

the septum when the vial is in said passive state, said triggering system allowing free access to said septum when the vial is in said active state. For example, the triggering system is configured so that the vial is moved from its passive state to its active state by pressure exerted on the vial by a user. For example, the triggering system comprises a first attaching member and a second attaching member axially spaced from each other, the vial being successively engageable with the first attaching member and with the second attaching member under pressure exerted by a user, said septum being not reachable by the needle of an injection device when the vial is engaged in said first attaching member, and said septum being reachable by the needle of an injection device when the vial is engaged in said second attaching member.

For example, the vial may need to be moved towards the distal end of the cavity in order to move from its passive state to its active state.

In embodiments not shown, the triggering system may be connected to, or part of, the counting system. In particular, when the counting system is an automatically activated one, as shown on Figure 16, the counting system may be activated by the triggering system when the vial is moved to its active state.

In embodiments not shown, the counting system may include a blocking member for preventing access to the septum by the needle of an injection device when a predetermined number of doses of product have been withdrawn from the vial.

In embodiments not shown, the assembly may comprise a time indicator for monitoring time elapsed since withdrawal of a first dose of product from the vial.

This time indicator may consist in a visual indicator for example with a change of color or with the evolution of a cursor or a fluid on an appropriate scale. This time indicator may also show if a temperature breach has occurred, it may show the cumulative amount of time during which the vial has been exposed to high temperature.

The time indicator may be activated either manually by the user, when the user activates the counting system such as the dose counter after the first withdrawal of a dose of product from the vial or when the user removes the assembly from the apparatus (see Figures 10 and 11) for the first time. In embodiments, the time indicator is activated by the triggering system.

After a specific period of time, which depends on the nature of product/drug stored in the medical container, the time indicator indicates to the user that the expiration date of the medical container has been reached.

In embodiments not shown, the time indicator comprises a locking member for preventing access to the septum by the needle of an injection device when a predetermined time has elapsed since withdrawal of a first dose of product

Any dose withdrawal beyond this specific period of time can also be prevented with a blocking system connected with the time indicator in order to prevent the removal of the housing out of the apparatus, when a specific number of doses have been withdrawn from the medical container.

The risk of administrating an expired drug to a patient is therefore greatly limited.

With reference to Figures 10 and 11 is shown an apparatus 400 according to the invention for storing at least one housing 100 or assembly 110 as described above.

The apparatus 400 comprises an enclosed storage chamber 401 comprising a cold storage accumulator 402.

The cold storage accumulator 402 may comprise active or passive technology.

A passive technology may be an open, insulated area to receive ice blocks, cold liquids or cooling packs such as bags filled with refrigerant. In this case, users fills the area before or immediately after receiving the housing and/or medical container inside the apparatus.

A passive technology may also consist in a totally or substantially closed area filled with refrigerant. In this alternative, the apparatus 400 is cooled in a freezer or in a cold area before or immediately after receiveing housings and/or medical containers. A substantially closed area may be provided with openings and optionnally internal tubings, in order to be connected to an external cooling system. Cool liquid produced by the external cooling system may then circulate in the cold storage accumulator to bring it to an optimal temperature, as for example 2 to 8 °C.

Refrigerants contained in the cold storage accumulator 402 are preferably non-toxic materials with a high enthalpy of fusion such as water, glycerol, parafin wax, fatty acids and combination thereof. Such materials may

also be in the form of gel when mixed with hydroxyethyl cellulose or vinyl-coated silica gel.

The cold storage accumulator may also incorporate an active technology as Peltier cells or endothermic reactions. Peltier cells absorb heat when submitted to power and endothermic reaction, such dissolving solid ammonium nitrate or ammonium chloride in water quickly cool surrounding environment. If such technologies are not sufficient to cool housings and/or medical containers for an extended period of time, they can be used in combination with passive technology in order to sustain a longer optimal temperature.

The cold storage accumulator may be integrated in the apparatus 400 or may consist in a removable part. Such a removable part may be preferable when a power supply or a cold storage is required.

The cold storage accumulator 402 comprises a series of openings 403 for receiving the housings 100 or assemblies 110 of Figures 2A-C and 9A-B. On the example shown the cold storage accumulator 402 comprises ten openings 403 for receiving ten housings/assemblies (100, 110). The housing 100 and assemblies 110 may be lodged inside the openings 403 in a removable way. Therefore, when a user needs to proceed to withdrawal of doses of product, he removes one assembly 110 from the apparatus 400 and leaves the other assemblies 110 therein. Therefore, while the user withdraws doses of product 6 from the vial 1 of the assembly 110 which has been removed from the apparatus 400, the other assemblies 110, which are lodged with contact with the cold storage accumulator 402 continue to store cooling capacity.

As shown on Figure 11, the cold storage accumulator 402 further comprises a central recess 404. This central recess 404 may be used for storing auxiliary recipients 500 as shown on Figures 12 and 13. The auxiliary recipients may be stored inside a box 501 received within the central recess 404. For example, the auxiliary recipients 500 may contain lyophilisate usable in cooperation with the product 6 contained in the vial 1 for example for reconstitution of a drug to be dispensed to a patient. The recess 404 may also be used for storing other kind of medical devices or recipients.

In embodiments not shown, the apparatus may further comprise an activation system for automatically activating the triggering system of an assembly when said assembly is removed from said apparatus : for example, a

plug present on the apparatus may cooperate with the triggering system and/or with the counting system of the assembly when the assembly is removed from the apparatus.

5 In embodiments not shown, the apparatus may further comprise a blocking system for preventing the removal of an assembly from the apparatus when a predetermined number of doses of product have been withdrawn from the vial received in said assembly.

10 In embodiments not shown, the apparatus may further comprise a time indicating system for monitoring time elapsed from removal of an assembly from the apparatus. This time indicating system may be activated by the first removal of said assembly from said apparatus. The time indicating system may comprise a locking system for preventing the removal of an assembly from the apparatus when a predetermined time has elapsed since first removal of said assembly from said apparatus.

15 With reference to Figures 14-16 is shown an adaptor 610 in which the counting system may be automatically incremented at each withdrawal of a dose of product.

The references designating the same elements as in Figures 5-7B have been maintained, augmented of 300.

20 With reference to Figures 14-16, the cap 640 comprises a tubular wall 642 closed at its proximal end by a transversal wall 641 provided with a central hole 643. The proximal face of the transversal wall 641 is provided with an opening 641b radially spaced with respect to the center of the transversal wall 641. The proximal face of the transversal wall 641 is further provided with
25 two holes 644 symmetrically located with respect to the central hole 643.

The gripping member 620 comprises a partially tubular wall 622 provided with radial rims 627.

30 The counting system comprises a flat cylinder 692 provided with a central through hole 694. The flat cylinder 692 comprises on its lateral wall two diametrically opposed outer pegs 693. From the distal face of the flat cylinder 692, extend in the distal direction three circumferentially distributed flexible rings 695, capable of collapsing when a distal pressure is exerted on the proximal face of the flat cylinder 692. The proximal face of the flat cylinder 692 is further provided with a plurality of circumferentially distributed information
35 data 696, such as digits from "0" to "10" on the example shown.

The counting system further comprises a ring 697 receiving the flat cylinder 692. The ring 697 is provided with a distal inner annular ridge 698 forming a distal abutment for the flat cylinder 692. The ring 697 is further provided on its lateral wall with a cam 699 forming a plurality of circumferentially distributed peaks 699a and valleys 699b.

When the adaptor 610 is assembled, the pegs 693 of the flat cylinder 692 are engaged in the cam 699 of the ring 697.

When the adaptor 610 is assembled and coupled onto the collar 3 of a vial 1, as shown on Figure 16, the flat cylinder 692 is received within the ring 697. The flat cylinder 692 is capable of rotating with respect to the ring 697, therefore with respect to transversal wall 641. Before use, one of the information data, for example digit "0" faces the opening 641b of the transversal wall 641 and it is therefore visible by the user.

For sake of clarity, Figure 15 shows the gripping member 620 and the counting system (flat cylinder 692 and ring 697) mounted on the vial 1 without the cap 640. Before any withdrawal of doses of product 6 from the vial 1, the position of the pegs 693 with respect to the cam 699 is as shown on this Figure 15 : each peg 693 faces a peak 699a.

With reference to Figure 16, the adaptor 610 is shown fully installed on the vial 1, with the cap 640, just before withdrawal of the first dose of product 6. On this Figure is also shown an activation member under the form of a plate 111 provided with a central hole 112 and with two pins 113 extending in the direction of the vial 1 and facing the two holes 644. The plate 111 is part of the housing 100 of Figure 2A-C, not shown on Figure 16 for sake of clarity, and it is coupled to the transversal wall 641 of the cap 640 via a helical spring 114, once the vial 1 and its adaptor 610 are fixedly lodged within the housing 100 (Figure 2A-C). On this Figure 16 is also shown partially the distal end of a needle hub 7 of an injection device and the needle 8 of this injection device.

When the user is ready to withdraw the first dose of product 6, he introduces the needle 8 inside the elastomeric piece 30 of the adaptor 610, then inside the septum 4 of the vial 1. By doing this, the needle hub 7 comes in contact with the edges of the central hole 112 of the plate 111 and applies a pressure on this plate 111 in the direction of the arrow F shown on Figure 16. Thanks to the helical spring 114, the pins 113 penetrate the two holes 644 and come in abutment onto the proximal face of the flat cylinder 692. The pins 113 exert a pressure on the flat cylinder 692 in the direction of the arrow F. Thanks

to the flexible rings 695, the flat cylinder 692 moves in the direction of the arrow F, and the peg 693 travels from a peak 699a to a valley 699b, thereby rotating the flat cylinder 692 with respect to the ring 697 and with respect to the transversal wall 641. The digit now appearing through the opening 641b of the
5 transversal wall 641 is "1".

Once the user has completed the withdrawal of the first dose of product 6, he removes the needle 8 and needle hub 7 of the injection device. Both the flexible rings 695 and the helical spring 114 come back to their respective rest position, and the peg 693 travels back from a valley 699b to the
10 next peak 699a, completing the partial rotation of the flat cylinder 692 corresponding to the withdrawal of the first dose of product. On this next peak 699a, the peg 693 is ready for the next withdrawal of dose product 6. Each time the user completes a withdrawal of product 6, the step described above is repeated, and the peg 693 moves from one peak to the adjacent one, thereby
15 automatically incrementing the counting system.

In another embodiment, the counting system may indicate the number of remaining doses in the medical container. In such a case, the digit indicated on the flat cylinder before any dose withdrawal corresponds to the maximum number of doses still contained in the medical container.

20 The housing, assembly and apparatus of the invention allow maintaining the temperature inside the medical container at a predetermined range optimal for the good and safe storage of a product contained therein, such as a vaccine.

Although the invention has been described in detail for the purpose
25 of illustration based on what is currently considered to be the most practical and preferred embodiments, it is to be understood that such detail is solely for that purpose and that the invention is not limited to the disclosed embodiments, but, on the contrary, is intended to cover modifications and equivalent arrangements that are within the spirit and scope of the appended claims. For
30 example, it is to be understood that the present invention contemplates that, to the extent possible, one or more features of any embodiment can be combined with one or more features of any other embodiment.

CLAIMS

1. A housing (100) for receiving a medical container (1) having a collar (3) closed by a septum (4), said housing comprising at least a wall (101) shaped and dimensioned so as to substantially surround said medical container while leaving free access to at least a portion of said septum, said housing further comprising a fixation system (106) for maintaining said medical container lodged within said housing, said wall being made of an insulating material.
2. A housing (100) according to claim 1, wherein said wall further includes a material capable of accumulating cold.
3. A housing (100) according to claim 1 or 2, wherein said wall comprises a plurality of insulating material layers.
4. A housing (100) according to claim 3, wherein at least two adjacent insulating material layers are separated by a layer of air or vacuum.
5. A housing (100) according to any one of claims 1 to 4, wherein the fixation system is selected from friction means, snap-fitting means (106), and combinations thereof.
6. A housing (100) according to any one of claims 1 to 5, wherein said wall comprises an opening (102) for engagement of the medical container inside said housing.
7. An assembly (110) comprising a housing (100) according to any one of claims 1 to 6 and a medical container having a collar (3) closed by a septum (4), wherein said medical container is received within said housing.
8. An assembly (110) according to claim 7, further comprising an adaptor (10; 310; 610) coupled on one hand to the collar of said medical container, and on the other hand to the fixation system of said housing.
9. An assembly according to claim 8, wherein said fixation system comprises snap-fitting means (106) for coupling said adaptor to said housing.
10. An assembly (110) according to claim 8 or 9, wherein said medical container being filled with a plurality of doses of product (6) to be withdrawn therefrom with an injection device, said adaptor comprises a counting system (91; 692, 697) for indicating how many doses of product have been withdrawn.
11. An assembly according to any one of claims 7 to 10, further comprising a triggering system, said medical container being in one of an active

or passive state with respect to said triggering system, said triggering system preventing access to said septum when said medical container is in said passive state, said triggering system allowing free access to said septum when said medical container is in said active state.

5 12. An assembly according to claim 11, wherein said triggering system is configured so that said medical container is moved from its passive state to its active state by pressure exerted on said medical container by a user.

10 13. An assembly according to any one of claims 10 to 12, wherein said counting system includes a blocking member for preventing access to the septum by the needle of an injection device when a predetermined number of doses of product have been withdrawn from the medical container.

15 14. An assembly according to any one of claims 7 to 13, further comprising a time indicator for monitoring time elapsed from withdrawal of a first dose of product from the medical container.

15 15. An assembly according to claims 11 and 14, wherein the time indicator is automatically activated by the triggering system.

20 16. An assembly according to claim 14 or 15, wherein the time indicator further comprises a locking member for preventing access to the septum by the needle of an injection device when a predetermined time has elapsed since withdrawal of a first dose of product.

25 17. An assembly (110) according to any one of claims 10 to 16, further comprising an activation member (111, 113) for operating the counting system automatically, said activation member being triggered by pressure exerted by a part of an injection device used for withdrawing a dose of product (6) from the medical container.

30 18. An apparatus (400) for storing at least one housing (100) according to any one of claims 1 to 6 or an assembly (110) according to any one of claims 7 to 17, comprising an enclosed storage chamber (401) comprising a cold storage accumulator (402), the cold storage accumulator including a series of openings (403) receiving a series of housings (100) according to claims 1-6 or assemblies (110) according to claims 7-17.

35 19. An apparatus (400) according to claim 18, wherein the cold storage accumulator further comprises a recess (404) for storing auxiliary medical recipients (500).

20. An apparatus (400) according to claim 18 or 19, further comprising an activation system for automatically activating the triggering system of an assembly when said assembly is removed from said apparatus.

5 21. An apparatus according to any one of claims 18 to 20, further comprising a blocking system for preventing the removal of an assembly from the apparatus when a predetermined number of doses of product have been withdrawn from the medical container received in said assembly.

10 22. An apparatus according to any one of claims 18 to 20, further comprising a time indicating system for monitoring time elapsed from removal of an assembly from the apparatus.

23. An apparatus according to claim 22, wherein said time indicating system is activated by the first removal of said assembly from said apparatus.

15 24. An apparatus according to claim 22 or 23, wherein said time indicating system comprises a locking system for preventing the removal of an assembly from the apparatus when a predetermined time has elapsed since first removal of said assembly from said apparatus.