Research for Development

Antonella Valeria Penati *Editor*

In-Home Medication

Integrating Multidisciplinary Perspectives in Design-Driven Pharma Practices

OPEN ACCESS

Research for Development

The series Research for Development serves as a vehicle for the presentation and dissemination of complex research and multidisciplinary projects. The published work is dedicated to fostering a high degree of innovation and to the sophisticated demonstration of new techniques or methods.

The aim of the Research for Development series is to promote well-balanced sustainable growth. This might take the form of measurable social and economic outcomes, in addition to environmental benefits, or improved efficiency in the use of resources; it might also involve an original mix of intervention schemes.

Research for Development focuses on the following topics and disciplines:

Urban regeneration and infrastructure, Info-mobility, transport, and logistics, Environment and the land, Cultural heritage and landscape, Energy, Innovation in processes and technologies, Applications of chemistry, materials, and nanotechnologies, Material science and biotechnology solutions, Physics results and related applications and aerospace, Ongoing training and continuing education.

Fondazione Politecnico di Milano collaborates as a special co-partner in this series by suggesting themes and evaluating proposals for new volumes. Research for Development addresses researchers, advanced graduate students, and policy and decision-makers around the world in government, industry, and civil society.

THE SERIES IS INDEXED IN SCOPUS

Antonella Valeria Penati
Editor

In-Home Medication

Integrating Multidisciplinary Perspectives in Design-Driven Pharma Practices

Editor
Antonella Valeria Penati
Department of Design
Politecnico di Milano
Milan, Italy

ISSN 2198-7300 ISSN 2198-7319 (electronic)
Research for Development
ISBN 978-3-031-53293-1 ISBN 978-3-031-53294-8 (eBook)
https://doi.org/10.1007/978-3-031-53294-8

Politecnico di Milano

This Springer imprint is published by the registered company Springer Nature Switzerland AG
The registered company address is: Gewerbestrasse 11, 6330 Cham, Switzerland

Contents

Chapter 17
Use Phenomenologies: What Does the User Do with the Secondary Medicine Packaging and Package Leaflet?

Antonella Valeria Penati

Abstract This chapter supplements the remarks contained in the paragraph *The role of medicine packaging in dispensing* of this text. In that context, we addressed the important role that secondary packaging plays in the dispensing process, especially in terms of its informational connotations. In this chapter, we look instead at the dynamics of patient use, once the medicine has entered the context of everyday use. In addition to the informational aspects, functional aspects such as opening, closing, containing, storing etc. come into play. It is in the relationship with the patient that the secondary pack demonstrates its informational and usage effectiveness. The medicines under analysis were 'taken' from the contexts of use under observation. To return the problems observed, the mode of illustration was chosen, eliminating the medicine's identifying marks, while leaving the description of the problematic elements, from our point of view, relating to information and form, which were returned in 'anonymous' form.

17.1 Secondary Medicine Packaging in Use

In the paragraph *The role of medicine packaging in dispensing* of this volume, we began our reading of the secondary packaging of medicines, starting with the studies that have had the pharmacist as the reference user for all those activities that involve high interaction with the medicine at the time of dispensing.

In the context of dispensing, the external packaging of the medicine-the secondary packaging in fact-takes, to all intents and purposes, the role of an object in and of itself, with a strong autonomy concerning the contents, which no one can access, not even the pharmacist, because of the seals imposed by the anti-tampering regulations (European Parliament (the), Directive 62/EU 2011).

A. V. Penati (✉)
Department of Design, Politecnico di Milano, Milan, Italy
e-mail: antonella.penati@polimi.it

A. V. Penati (ed.), *In-Home Medication*, Research for Development,
https://doi.org/10.1007/978-3-031-53294-8_17

At the dispensing stage, as we highlighted in the part of the text mentioned above, the clarity of the multiple information elements that cover the entire surface of the packaging is especially relevant. Each of these is of fundamental importance in the process that leads to the unambiguous identification of the medicine to be dispensed, distinguishing it from others by name, the dosage of the active ingredient, number of doses contained, pharmaceutical form, etc. In the pharmacy, the packaging certainly does not lose its value as a container. Still, this function becomes, as to say, secondary to the visual component because it is in the design of the information elements that the functional effectiveness of the secondary packaging is expressed.

As soon as the medicine enters the patient's sphere of use, not only does the packaging fully manifest and tangibly acquire all its functional prerogatives (containing, preserving, shaping, facilitating access to the contents, dosing, informing, etc.), but the information apparatus itself and even the way it is 'put on the page', in the patient's sphere of use, assume a different utility concerning the specific needs of those who dispense the medicine.

As is well known, the information necessary to correctly identify a medicine is regulated, as well as specific principles of a hierarchical arrangement of information on the page are recommended, and also what information must necessarily be on the main page of the packaging and, according to what logic, some of it must be close to each other, to create connections of meaning (European Parliament, Directive 2001/83/EC, art 54).

Similarly, specific Guidelines are now well-established that suggest the most appropriate ways for the informational use of images and pictograms that can supplement, but not replace, verbal information (European Parliament, Directive 2001/83/EC, art 62).

Yet even though the repertoire of recommendations has grown over time, primarily due to user experience and its incorporation and transformation into precept for proper design, there remain many gaps in the effectiveness of the information elements accompanying the medicine in appropriate use.

For example, our observations show that, for the user, the name of the medicine and its active ingredient, so crucial to the pharmacist, have little effectiveness to remember the pathology, the organ, and the reason why that medicine is taken. Even more so, in occasional-use medicines—such as an antibiotic—a long time after its use, patients are not even able to remember why that medicine was prescribed, by what doctor, and under what circumstances. This is precisely why, on the secondary packaging, the patient is used to making notes (Fig. 17.1), especially at the beginning of the therapy and before becoming familiar with it. These are annotations related to the patient's name (in case two or more patients are taking medicine in the house); the reason why the medicine was prescribed (translating into familiar language abstract designations and ineffective in reconnecting the name to the reasons for its assumption, for example: *Warfarin Sodico*, 'anticoagulant'; or *Amiodarone Cloridrato*, 'for the heart'; *Perindopril Arginina e Amlodipina*, 'for blood pressure'; *Sodio Alginato e Sodio Bicarbonato*, 'for digestion'; to the dose of medicine that is to be taken (this is especially the case when several doses are taken within the day or fractions of the single dose or different doses on different days); to the date of

Fig. 17.1 Example of notations written by patients on medicine packages to customise them according to medical prescriptions

Fig. 17.2 Examples of medicine packaging in which there is a space inviting customisation through user information

opening the pack or starting therapy to verify compliance with shelf life or adherence to the prescribed dosage. In other words, the secondary pack becomes, for the patient, 'the blackboard', the 'calendar', the 'post-it' on which to note information able to personalize its use.

Some pharmaceutical companies, having picked up on this need of the patient to integrate general information with information related to personal therapy, have begun to expressly provide in secondary packaging, spaces dedicated to user notes (Fig. 17.2).

Again, from the interviews conducted with patients, it emerges that, in the custom that accompanies the daily intake of medicine, it is not so much the "registry" elements that the patient refers to distinguish one medicine from another-as is the case in pharmacies-, but instead it is the overall graphic elements that are grasped by the patient 'at a glance'. In daily practice, the medicines in use are often arranged in a specific order (mainly when the therapy consists of many drugs) and are managed according to intake sequences that, once set, are repeated daily through semi-automatic actions. The order and sequences of gestures regulate the taking practices and not the analytical recognition of the information elements that identify the individual medicine. The patient uses a careful reading of the medicine's master data at crucial moments, such as changing therapy, ending a medicine and replacing it with refills, etc.

Paradigmatic of this behaviour is the story of a patient who, in a moment of inattention, did not put his usual medicine—the active ingredient of which is *Clonazepam*—in the kitchen drawer reserved for his therapy, but left it on a shelf, next to the medicines used by his wife. Among the medicines in his wife's therapy was a medicine whose active ingredient is *Bromazepam*, a medicine with secondary packaging bearing a strong visual similarity to the former (Fig. 17.3). Both medicines, in fact, despite having distinct proprietary names and not belonging to the same corporate brand, have a very similar overall image, especially at the top of the opening. This organisational defaillance is said to have caused a serious intake error, which was fortunately prevented by the different olfactory impression of the two solutions and the speed at which the drops came out, which made the user suspicious of a possible packaging mix-up.

While many patients report that they carefully observe the information related to the 'drug registry' only on particular occasions, even more report that they do not read at all the information on the secondary packaging associated with instructions for use, storage regulations, precautions related to securing the medicine, etc. From the experiences collected, some users even 'get rid' of the secondary pack when they put the

Fig. 17.3 Medicines with a different name and different active ingredient but easily confused by the graphics of the case

medicine in the containers they use to organize home therapy keeping only the primary pack. Even the package leaflets are often thrown away without even being read. Sometimes the secondary pack is thrown away, while the package leaflets are stored separately from the medicines (e.g., in drawers used for collecting medical documents and filed meticulously inside transparent envelopes); sometimes. They are stored in bulk inside bags (Fig. 17.4). But the practice of having 'naked medicine' with only the primary packaging is widespread, especially in the case of blister packaging.

Several hypotheses can be made about why patients do not read the information in the secondary pack of medicines. Indeed, the most plausible, confirmed by the patients interviewed, lies in the belief that all helpful information is contained in the Package Leaflet. Then there is, especially among the elderly, the sense of respect for the doctor's authority and trust in the indications received from him. These would not make further information necessary. There is probably also a behaviour derived from the habits of using packages of other products to which we rarely pay attention except for the little information searched for on first use.

One can suppose that underlying this distracted attitude is also the ambiguity of the addressee to whom the information on the secondary pack is addressed: in fact, it is not very clear which ones pertain to the Pharmacist and which ones are intended for the user-patient.

An additional problem probably needs to be considered: the temporal inconsistency between the time of reading the information and the time of use. Some of the information available on the secondary pack concerns how to conserve the package before use, the possible effects of taking medicine; and the post-use and disposal phases.

Mainly, the user tends to read the information found on the package, at the time of its opening, which often coincides with using the contained product. Utilitarian logic prompts the patient to read only when the need for information emerges. This a condition that, by analogy with most everyday products, may not even arise because custom tends to shape user behaviour. Unfortunately, in the case of medicines, reliance on custom, can produce even serious errors. For this reason, all the indications on secondary packaging, which the user should apprehend before use, should be rethought from the formal point of view to have greater visibility and ability to attract attention.

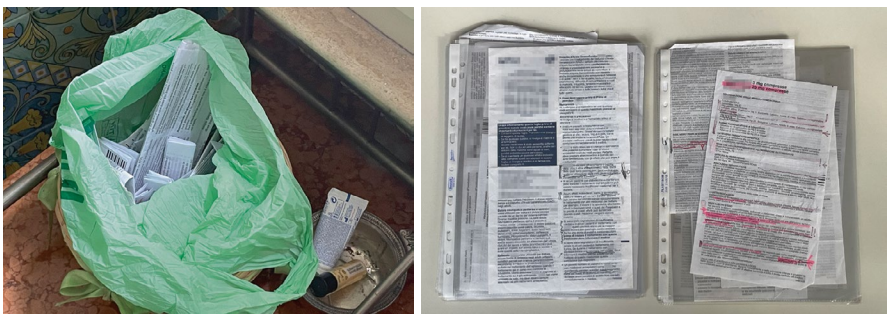

Fig. 17.4 User behaviour when using packaging leaflets

As well as should be present on the secondary pack and have visibility of all those useful information even before the purchase: intolerances; size of solid oral forms when they could create swallowing difficulties; prohibition of use or attention to use in children or pregnant women, or the elderly, etc. This applies, in a particular way, to non-prescription medicines that might have adverse effects for some patients. And these directions are even more necessary because the inner contents of the medicine cannot be inspected, and therefore the content of the information that must be placed on the outside of the product must also be carefully rethought.

We emphasise here the importance of depicting on the secondary packaging the shape and size, in real scale of the medicine contained, especially when it is a solid form for oral use. Indeed, many patients have difficulty swallowing and the impossibility of opening the secondary packaging makes it difficult to assess the ability to take the drug. It is not uncommon that, especially in the elderly patient, precisely because of the size of the medicine, there is a need for manipulation (crushing, splitting, etc.) of the medicine, sometimes improperly. Sometimes there is even a necessity to change medicine, throwing away, in effect, the pack that was mistakenly purchased due to insufficient information.

Currently, on the secondary packaging of medicines, the representation of the shape of the tablet contained is either missing altogether or, as sometimes happens, is represented with a three-dimensional image that does not necessarily refer to the real shape of the medicine contained (Fig. 17.5). Indeed, in many cases, these images generically allude to the fact that the content is an oral solid form, but this image does not necessarily correspond to the content.

In this regard, in addition to adding a realistic representation of the content (correctly representing the actual tablet shape and size), consideration should also be

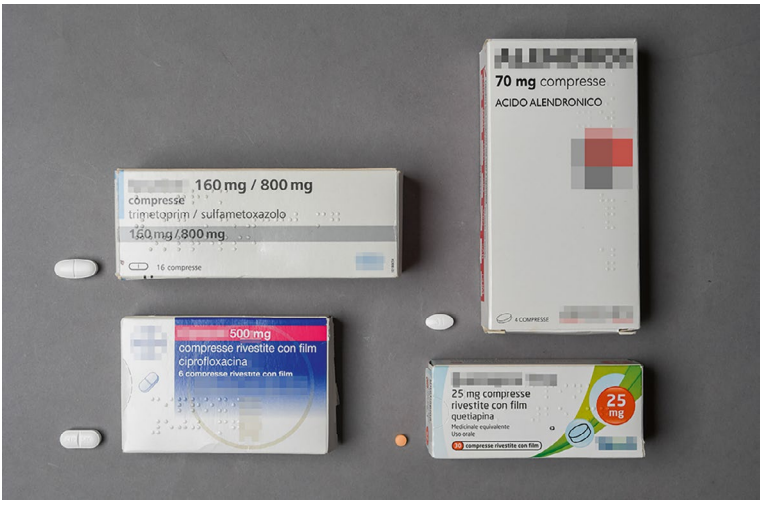

Fig. 17.5 Examples of medicines in which the representation of the medicine on the secondary pack does not correspond to the size of the contained medicine. The illustration is only intended to indicate to the user the type of medicine contained, not its actual characteristics

given to reviewing/prohibiting the use of images, included in the pack for purely advertising purposes, where these may lead the user to misinterpret the pharmaceutical form contained. Two examples are illustrated below (Fig. 17.6), chosen from among many on the secondary packaging of medicines. In the first case, a tablet is represented leaving a trail; in the second case, the name of the medicine is 'decorated' with a cloud of circles of different sizes. The intention is probably to represent the beneficial force released by the medicine. These images, however, may evoke the trail of bubbles typical of effervescent tablets. Whereas the medicines in question are coated tablets that must be swallowed while drinking water.

A final example is those corporate brands that resemble or can be traced back to pharmaceutical forms (Fig. 17.7). These graphic elements risk confusing the user as to the form of the medicine contained and may even be confused with operational indications that the user should/could make on the medicine. We refer here in particular to labels that have great similarities with typical tablet representations. The ambiguity generated by the mark, due to its shape, can be further amplified by the fact that, on the medicine's packaging, the mark is not positioned next to the company's logo, to constitute a communicative unit, but is placed in an isolated position. This makes it difficult to assume that the visual sign of the trademark is part of the corporate image system and the user might instead interpret that sign as an indication of the fractionability of the contained medicine.

We add a reflection here. Medicine does not represent a consumer good that motivates the user to purchase it. Users don't choose the medicine: it is prescribed and represents a necessity for the patient. It is also necessary to consider the "passive

Fig. 17.6 Examples of images that may confuse the user as to how to assume

Fig. 17.7 Fictitious examples of company brands (simulating existing brands) that refer to the tablet/capsule form and may therefore confuse the user. It should be noted that these trademarks referring to a solid oral form may also be present on packages containing drops, syrups, etc.

purchase" condition in the lack of 'informational curiosity'. A curiosity that instead the consumer shows for the products he purchases motivated by needs or desires. Even in the case of ordinary consumer products, however, of the information on the packaging, only that which interests the user at first use is sought. If they are goods for continuous use, the information on the packaging is no longer re-read in subsequent uses. In medicine, conversely, we are faced with a wrapper that is as important as the product it contains, constituting, with its information, an integral part of it. For some of these, the patient may need to access it several times during therapy. It is crucial to consider the processual aspects involving the communicative elements. Indeed, one can speak of a kind of "communication life cycle" that follows—or instead should follow—the life cycle of a medicine, emphasizing different information based on the information necessity that may be different at other times during therapy:

- the medicine is being taken for the first time by a neophyte patient who has no information about how to use it, how to store it, how it interacts with other medicines or food and drink, and any adverse effects, and for whom it is necessary to assess what "initiation of therapy" information needs to be accessed as a priority to facilitate the experience of treatment;
- the medicine has been taken for some time because it is part of the daily therapy of a patient who can be defined as an "expert"—in the etymological sense of one who has gained experience and therefore needs unique information generally related to particular situations or eventualities;
- the medicine is taken occasionally or is prescribed sometime after the first intake, a type of use this lends itself to various errors related to the mixture of erroneous memories, forgetfulness, etc.

Precisely because the patient's knowledge about the medicine changes over time, special attention should be given to those information items that, especially at first use, need a didactic level of explanation. One example is the way of taking medicine, which is usually communicated with short formulations (e.g., "Medicine for oral use" or even just "Oral use"). These brief indications are understood not necessarily by everyone. This is further compounded by the fact that the modes of oral intake are different. Usually, this difference is indicated through an additional indication, separate from the previous one, which in the formulas "Film-coated tablets"; "Gastro-resistant tablets"; "Extended-release tablets," etc., subtend different ways of taking a medicine orally. Indeed, in some cases, the medicine does not need to be handled and can only be swallowed with water. In other cases, however, the tablets can be broken, crushed and even dissolved in water. In still other cases, they must be held in the mouth until dissolved. This modality is referred to by terms such as—orosoluble, orodispersible, and sublingual. The user does not always understand the differences between these definitions. This same information should also be found inside in a more articulated form. Thus, attention should be paid to indications related to the use of medicines, such as preparations in drops or powders in sachets, which, not possessing a form that unambiguously associates them with a route of intake, can give rise to even serious errors.

Secondary pack information, additionally, should be grouped into "sense areas" for the user and the actions he needs to take and be positioned at the point closest to the action to be performed (Fig. 17.8).

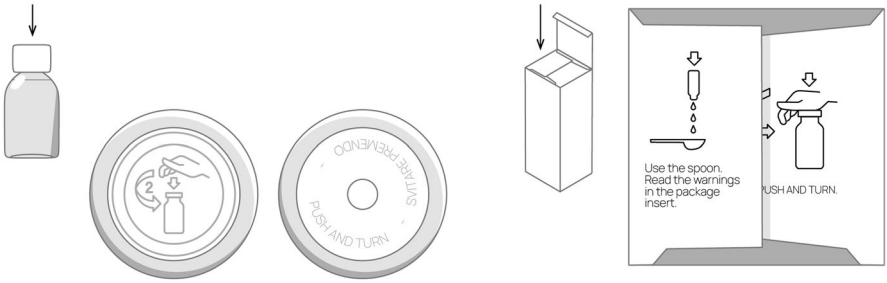

Fig. 17.8 Examples of spatial positioning of information that supports the user's action and precedes the action to be performed in a time-correct manner. The illustrations shown in the second example (on the right) are on the flaps of the packaging. Their purpose is to indicate the sequence of actions that the user must perform: (1) press and rotate the cap to open; (2) pour the drops by counting them. The logical sequence would be more correctly represented by inverting the position of the images and positioning action (1) on the left and action (2) on the right

From a communication perspective, the medicine package is presented as a complex artefact with layered information: partly arranged on the secondary package, partly on the primary package, partly on the package leaflet, and partly on the medicine itself. This layering does not always correspond to the user's information needs, which change depending on the user's experience of use.

And finally, the information on pharmaceutical product packaging does not always follow communicative hierarchies that can facilitate the user's information experience by guiding their reading. This observation applies to the disposition of information both between inside and outside the packaging and on the outside, that is, on the different faces of the secondary packaging.

Secondary packaging, in most cases, is shaped like a rectangle parallelepiped (Fig. 17.9). The dimensions of the different sides of the parallelepiped are, in addition to the graphic layout, essential elements in identifying the front and back of the packaging. In the case of parallelepipeds with two predominantly sized faces, recognition of the 'main page' is intuitive (most horizontally developed packages are included in this typology, characterized by two large-sized faces that serve as the front and back; two intermediate-sized faces that constitute the edge sides of the packaging; and two smaller sized faces that generally correspond to the opening/closing flaps). It is not as intuitive to identify the main face in the case of packages with four faces of the same size. Such are, for example, packages of vertically developed medicines (syrup packs, eye drops, drops, etc.) in which the two smaller faces constitute respectively the base of support (unusable from the communicative point of view) and the top, the part intended for the opening/closing of the package that the user sometimes tends to tear off to hand it over to the doctor or pharmacist when he runs out of medicine, and there is a need to buy a refill.

In the case of solids with the longest side on the horizontal plane (Fig. 17.10), the user knows, by custom, what information he will find on the main page: name of the medicine, active ingredient, dosage, amount of product contained, pharmaceutical form, route of intake, brand logo and brand name. On the back is an area for the

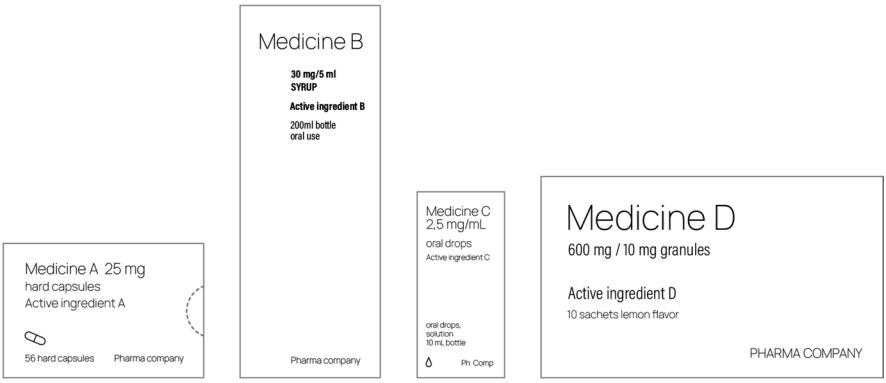

Fig. 17.9 Illustration of the main types of secondary packaging: the first is typical of medicines in blister packs, which, although of different sizes, are characterised by a side opening; the other type (characterised by an opening from the top) is typical of syrups, little bottles containing drops, and packaging of medicines in sachets

Fig. 17.10 The image, although illustrated by a fictitious medicine, reproduces the layout of a real medicine package on the market. The example demonstrates the irrational placement of information on the outer packaging

pharmacist, where there is the sticker by legal duty. All the information required by law and which the law itself suggests should be placed on the main faces of the packaging (e.g., *To be sold on prescription*; *Keep out of sight and reach of children*; *Read package leaflet before use*; *Do not dispose of container in the environment*, etc.) are not necessarily found on the back page, although, for the user, this is the most intuitive side where to look for them, in terms of size and therefore importance of the page.

In addition to the problematic traceability of the information contents (not always arranged in a hierarchical order and not present in a precise place in the packaging), these are in any case underestimated by patients because they have now entered into everyday use and our daily language to the point that their prescriptive importance is weakened. Many of the prescriptive contents we find in the packaging, for example, are part of advertisements during which they are read, at the close of the spot, at such a speed as to make them almost incomprehensible, thus giving the idea that they are ancillary messages of secondary importance. The graphic way this

information is presented in the packaging diminishes its content, with no specific order being present and none of the many artifices that the graphic treatment of a text makes available to create visual hierarchies and points of attention being used. Nor are they necessarily found on the main pages of the packaging but are sometimes placed on the minor sides. In addition, the randomness in the use of capitals, boldface, use of colour; the absence sometimes of interlines that distance the different 'warnings' (Fig. 17.11), making them perceived in their autonomy; the presence of text written vertically on a horizontal page (forcing the patient to rotate the packaging to read the text); the use of a reduced font body that is not sufficiently contrasted by the background colours or illegible because it is on a dark background, are all elements that contribute to weakening the 'appeal' contained in these prescriptive propositions. The perception of certain randomness seems to stem from 'filling' the available space more than from a communication design that is attentive to the reader's reading paths and need for comprehension. The area given to a corporate image, which can come to dominate and take a back seat to informational and prescriptive elements, also plays a significant role in this.

Fig. 17.11 The image illustrates a few examples of the graphic layout of the warnings from which various readability problems may arise: (1) most examples show that the back of the packet is used in few cases to give information to the patient; smaller sides where the body of the character is of necessity reduced are favoured for this purpose; (2) each pharmaceutical company decides autonomously what prominence to give to the different contents (laid down by law), through the use of capital letters, bold type, red colour, frames etc., in order to give a different relevance to the information for the user; (3) the individual warnings are hardly ever perceived independently through the use of appropriate interlineations; (4) in addition to the size of the font, the contrast between text and background also intervenes to reduce the readability of the information; (5) information on the presence of substances that must be well highlighted for certain patient groups (e.g. lactose), indistinct from general warnings such as 'keep out of the sight and reach of children'

Sometimes the language of the indications is also not immediately understandable due to the positioning on the secondary pack. An example is the sentence, "*The expiration date indicated refers to the product in intact, properly stored packaging*," which directs the patient's attention to problems with the integrity of the packaging as a whole and not the integrity of individual doses. And in fact, it is a widespread practice among patients to 'unblister' (a week, sometimes even a fortnight before use) tablets, pills, capsules, etc., interrupting the protection given by the primary pack.

The same warning, carried on the primary pack, may be more effective in influencing user behaviour.

Similarly, the phrase: Store in the original package to protect the product from light and humidity at a temperature not exceeding 25 °C. contains three different indications:

- the product must be protected from light (the secondary pack should provide this, and sometimes the primary pack when it is opaque or dark);
- the product must be protected from humidity (the primary pack should provide this); and
- the product must be protected from temperatures above 25 °C, and for this purpose, the pack proves to be an insufficient device because the only expedient the user can take is to store the medicine in a temperature-controlled place. The fact that the firm has fulfilled its informational obligations does not mean that it has made the user understand what concrete actions the user must take to ensure the integrity of the medicine. Moreover, the fact that this indication appears on a minor side of the package, along with other information that is important to the user but not at all distinguishable from each other, only distances it from the goal that should be a priority: to give adequate information to induce correct behaviour.

From the various reasons listed above, although summarily, it can be understood why so much information reported in the secondary pack is not perceived in its importance or even read.

17.2 Opening and Closing Signs

Observing user behaviour, we also note that, very often, the secondary packaging did not unambiguously indicate the correct side of opening. In a population that is 90% right-handed overall, the natural opening direction of a horizontal pack with side openings should be the right side. And on this side one would expect to find some clear indication for the user. Instead, it is rare for the words 'open here' to appear on medicine packs. Sometimes it is the die-cut mark that generates an invitation to open. Sometimes it is the tamper-evident seal indicating that that is the side to be opened by cutting the seal. it is an implicit indication and, as such, weak. Sometimes it is the die-cutting that tells the user that they have to tear the cardboard in order to open (Figs. 17.12 and 17.13).

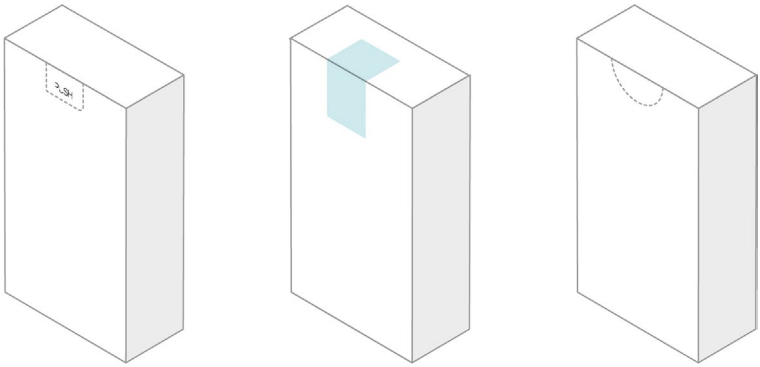

Fig. 17.12 Types of opening with greater or lesser capacity to properly guide the user's gestures

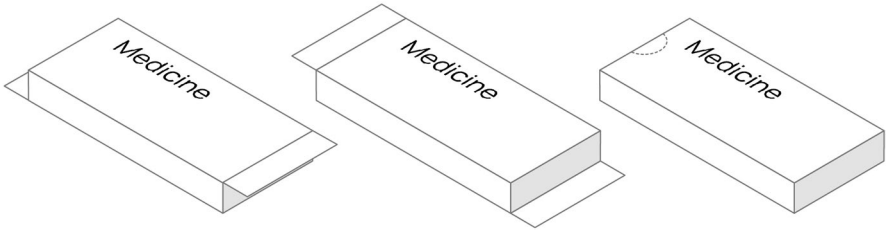

Fig. 17.13 Variety of box openings with different levels of difficulty for the user, because the opening is not visible or because the opening is on the wrong side

Sometimes, it is the shadow line generated at the top of the right side that makes the gap between the upper face and the side closing flap intuitable. When the opening is on the upper side, it not only attracts attention through sight, but also indulges the opening gesture with the thumb. Opening on the left side, on the other hand, is discouraged when the closing flap fits at the bottom of the pack, effectively disappearing and offering no invitation to use, even for the hand. In all these cases, however, these are weak invitations, not even explicitly designed to achieve the required action. Even on these seemingly minor aspects of operation, alternate design attention is devoted by the pharmaceutical industry. In some cases, the packaging design becomes refined, going so far as to produce a double layer of cardboard on the closure flap, so that the top layer, bearing the medicine data, can be removed and handed to the doctor for the next prescription. This is a clever redesign of the closure flap, redesigned to comply with the legal requirement to have tamper-resistant closures, at the same time, panders to the practice in use by patients of tearing/cutting off the opening flap containing the necessary data to be handed over to the doctor for the prescription of the following doses. But the cutting of the secondary pack to pick up a small label containing the master data of the medicine, is also used by the patient to report on the daily therapy sheets the visual elements of the packaging to make it easier to choose the suitable pack, among the many in the therapy (Figs. 17.14, 17.15 and 17.16).

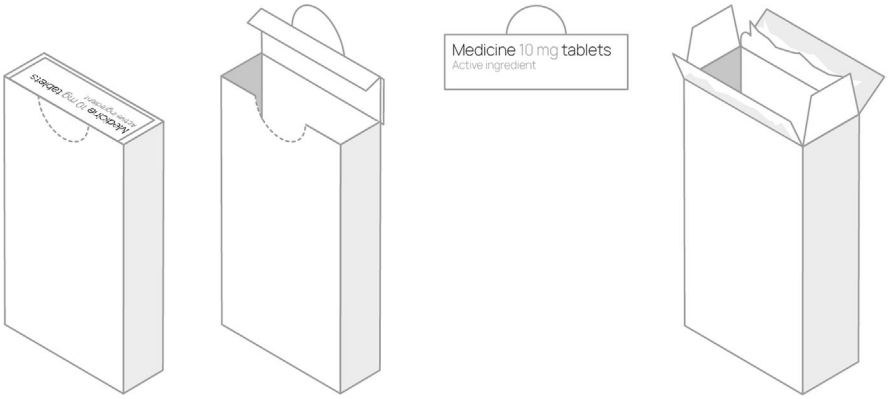

Fig. 17.14 On the left, detail of opening with flap joined to the packet by a die-cut; the flap can be separated from the packet so that it can be used as a tag to be shown to the doctor for subsequent prescriptions. On the right opening flaps closed with a glue stitch. Once opened, the pack cannot be resealed

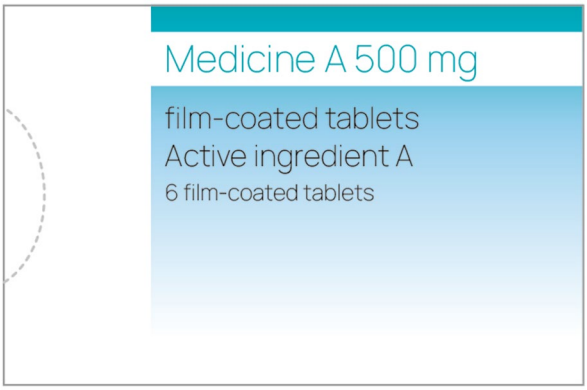

Fig. 17.15 Packaging designed to be opened on the left side with a die-cut invite

In the face of a few exemplary cases, we find closures obtained with a glue stitch that, once opened, can no longer be closed again, giving a "sloppy" and worthless impression to the container and its role and to the medicine contained. It is closures such as these that do not allow for all the tasks that are sometimes assigned to secondary pharmaceutical packaging: keeping in the dark some medicines that should not be exposed to light for too long; storing any medicine fragments dispersed in the package; making access somewhat less easy for children who might be more attracted to exploring the inside of an open package.

Even the opening from above, which would seem to pose less of a problem by indicating a quasi-obligatory action, nevertheless shows similar inattention to the patient's gestures.

Fig. 17.16 On the left the syrup package with the correct opening of the top. In the centre packaging containing powder in sachets, with the top opening from the back towards the front. In doing so, the user turns the packet over, thus losing information about the pharma they are taking. The third picture even shows the same situation as the pack in the centre, but on opening, the cover graphic appears 'upside down'

If the format of the medicine cases falls within the two case histories, we have seen—parallelepiped with predominantly horizontal development and opening at the side and parallelepiped with predominantly vertical development and opening at the top—some medicines present a certain ambiguity in this respect.

We report below two packs whose graphics and position of the opening follow the behaviour of vertically developed packs, although they have a geometric shape and therefore a mode of placement in drawers and shelves typical of horizontally developed boxes (Fig. 17.17). This generates perplexity in the user on the opening side.

This insistence on designing proper accessibility to the contents, in the case of medicine, is of particular importance not only for the apparent reason of making it easy for people, often the elderly, to access necessary and, in some cases, life-saving products, but also because it is essential to establish, perhaps even to regulate, whether the patient should find the medicine right away or, before accessing the medicine, should 'encounter' the Package Leaflet.

Again, the case is varied and is dictated by the requirements of the packaging system. In fact, at the stage of inserting the medicine and package leaflet inside its primary pack, the packaging machines, after folding the Package Leaflet, give it the characteristic open C shape with a final folding. Inside this "C shape" formed by the Package Leaflet, the blister packs (in the case of tablets) are threaded, and the package leaflet and blister are placed in the secondary packaging together. At this point, the secondary packaging is ready to be sealed.

Fig. 17.17 On the left, the packaging shape suggests an opening on the right side. The graphics are designed as if the pack opened from the top. On the right, the pack graphic indicates an opening from the top. Indeed, the packaging opens from the top. Nevertheless, the packaging shape would find a more appropriate opening placement on the right side

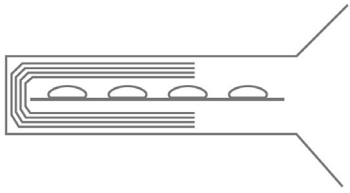

Fig. 17.18 Pack opening on the right with package leaflet on the left. The user does not see the package leaflet. If he wants to read it, he must remove both blisters from the pack

What sequences of action can the user follow when opening the medicine package? The first situation in which the user may find himself is immediately seeing the blister packs, slipping them out of the secondary packaging, and starting therapy without needing to take out the package leaflet that remains at the bottom. In this first situation, the user may not even see the package leaflet and, therefore, may not need to read it before taking medicine (Fig. 17.18).

If interested in reading the information about the medicine, before the start of therapy, the user can open the packaging from the left side and slide out the package leaflet or take out, from the right side, the entire contents, namely both the package leaflet and the blister packs. In this first scheme of element arrangement, the reinsertion of the blisters within the packaging is not easy because the package leaflet obstructs it. It happens when the blister is made of soft, pliable materials (e.g., aluminium-aluminium) that flex easily (Fig. 17.19).

Getting the blister back into its 'natural seat' is not easy in this case. This same difficulty also occurs when the patient has opened the package leaflet. After opened, it is difficult to fold the package leaflet back into the exact same starting shape and compact thickness as before the opening. This discomfort, according to patients, is one of the reasons why there is such a strong tendency to get rid of the leaflet or, if one is scrupulous, to store it in a different place than the secondary packaging. The proposed example concerns blister packs, but the same situation is also found in syrup or eye drops package.

The second pattern of the internal arrangement of blister packs and the related leaflet is when the patient, upon opening, first finds the package leaflet that 'wraps' the medicine blisters (Fig. 17.20). In this scheme, taking out the package leaflet is a necessary step to 'get to' the medicine.

Suppose it does not necessarily involve the patient reading the information. In that case, arranging the different internal elements ensures the right path the user should take to take a medicine correctly. Some patients (especially those who are used to not reading the leaflet) said they were irritated by this 'barrier' to the immediate use of the medicine. And indeed, a small percentage claimed that they felt a real discomfort and therefore eliminated the package leaflet from the secondary container for this very reason (Fig. 17.21).

However, this is the correct arrangement of the elements that compose the package and the one best suited to make the patient perform the correct sequence of actions. Even with this second scheme, in any case, the problems of reinserting the blister packs and package leaflet, remain unchanged.

Similar problems are encountered with upright, top-opening packages: syrups, drops, single-dose sachets (Fig. 17.22). Here too, where the package leaflet is placed underneath the medicine, the patient has to take it out in order to read the package leaflet.

This reflection drawn from the observation of ambivalent user behaviour allows us to highlight how seemingly minor aspects-in the case observed the arrangement

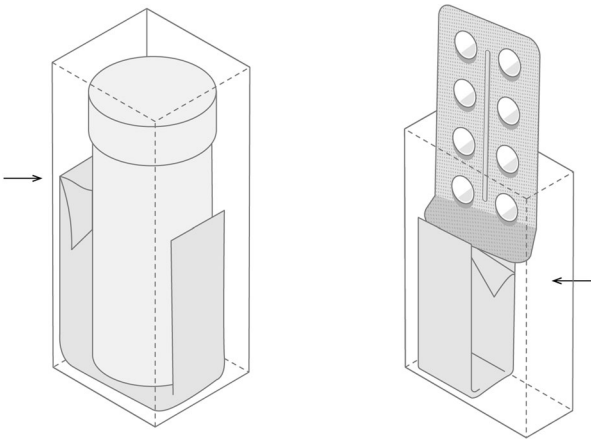

Fig. 17.19 Possible interference of the package leaflet in the removal and reinsertion of the primary pack into the secondary pack

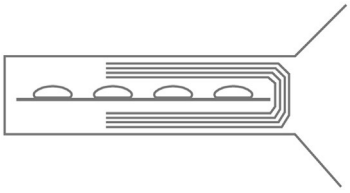

Fig. 17.20 Pack opening on the right with package leaflet on the right. The user has to get in touch with the package leaflet to access the medicine

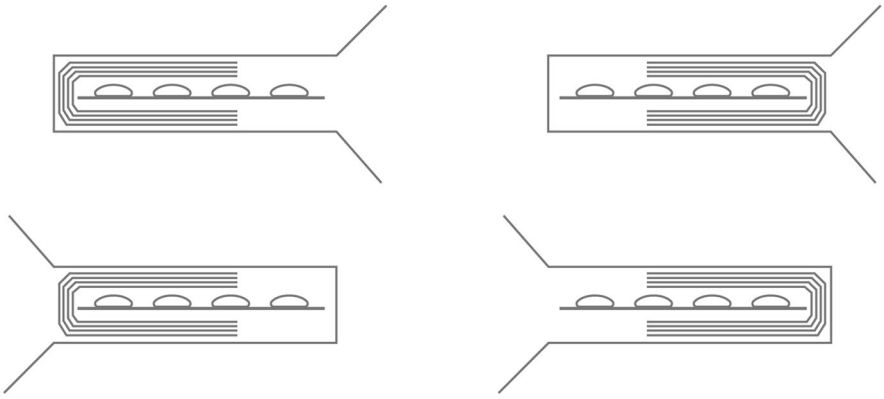

Fig. 17.21 The opening patterns currently on the market show that there is no designed relationship between opening side and package leaflet placement

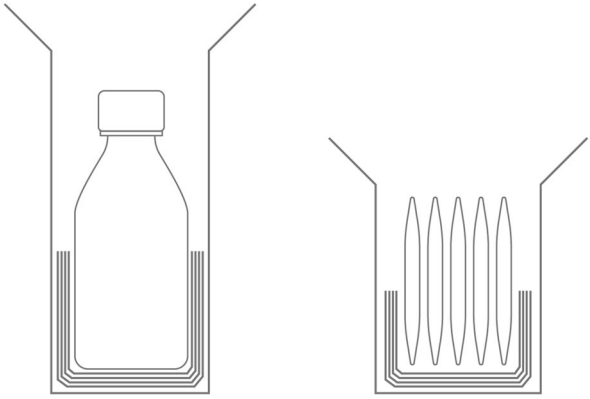

Fig. 17.22 Schematic representation of the different pack types with opening from above and package leaflet at the base. The case of sachets containing granules, powders or gel preparations well represents the discomfort of the user having to extract the entire contents to access the package leaflet

of the different product components within the package-can create obligatory or strongly pre-determined action sequences, thus influencing patient behaviour.

Indeed, as on many other aspects, there is a lack of deep user analysis that could give useful design guidance to make the medicine use experience more effective and easier, perhaps going so far as to change the folding pattern and placement of information content within the package.

17.3 Secondary Packaging and Primary Packaging: Visual Identity

It is good practice, we know, that secondary packaging, primary packaging, package leaflet and medicine are never separated. We know equally well, however, that this does not happen in the user experience. Leaving aside the misbehaviour which, we

have seen, punctuates the user experience, there is however a moment when, correctly, medicine, primary pack and secondary pack are separated. This is the moment when the medicine is taken. In complex therapies it may happen that the user, once the primary pack has been removed from its outer packaging, is no longer able to recognise the medicine. As we described in Chap. 12, medicines (especially oral solid forms) have a low degree of morphological differentiation and this is one of the causes that may lead to the medicine not being recognised once it has been removed from the secondary pack and blister. Sometimes, however, it is also the primary packaging that has insufficient identifying features and is poorly differentiated and/or does not carry the information necessary for the correct recognition of the medicine. Single-dose eye drops are an example of how difficult it is to recognise the medicine being taken once it has been taken out of its packaging. But the world of blister tablets itself is not immune to this problem. In fact, it can happen that the information about the medicine is not written on the aluminium foil that closes the blister pack, with sufficient frequency (Fig. 17.23).

Opening the tablets, by tearing the aluminium foil, has the effect of removing the information written on the foil. The Guidelines of the European Community recommend precisely in this regard that the frequency of the written information be carefully considered so that the medicine remains recognisable until the end.

It is therefore necessary that between secondary pack, primary pack and, if possible, medicine there are graphic elements (e.g., colour, graphics of the written parts etc.) that visually connect the different elements of the pack.

A second element which can confuse patients as to the recognisability of the medicine, especially patients taking the same medicine at different dosages throughout the day, is the lack of visual identity between secondary and primary packaging and drug. The use of certain colours on the outer packaging is sometimes not accompanied—or even contradicted—using an identical colour on the medicine as well. The example below, we believe, eloquently illustrates the difficulty in recognising the medicine that the user may encounter (Fig. 17.24). The example illustrates just

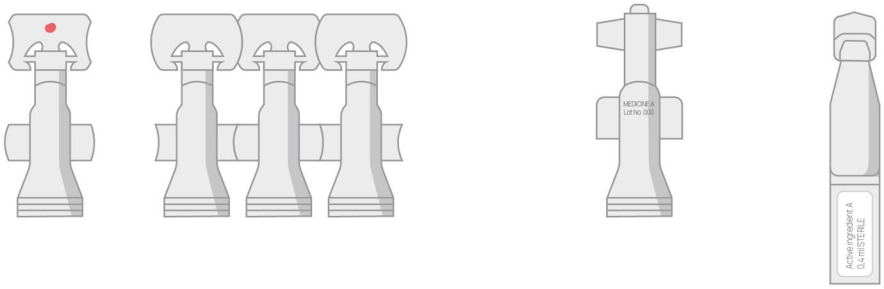

Fig. 17.23 On the left, marks made by the patient to distinguish two eye drops (one of which is a cortisone with limits on daily dosage) with too similar primary packs and with the brand name of the drug almost invisible. The patient covered the cap of one of the two packs with paper scotch on which he drew a small mark. On the right is an ex-ample of a primary pack of an eye drop that not only ensures better prehension, but also provides a space to give the correct information about the medicine's name

Fig. 17.24 Example of a medicine with multiple dosages. The colour variations indicating the progressive increase in dosage in the secondary pack are not well 'interpreted' using different colours which have little meaning for either the pharmacist or the patient (they are in fact neither colours in chromatic contrast nor colours in chromatic progression). Similarly, the capsules are not able to communicate the progression of the different dosages. In addition, there is no colour relationship between secondary packaging and capsules

as clearly the lack of a criterion for translating the increase/difference in dosages of the same medicine through the use of colour. This applies both to capsules, compared with each other, and to secondary packages, compared with each other. As the dosage of the active ingredient increases, one might expect a 'crescendo' colour transition on the same colour scale (on the use of colour in the world of medicine, see Chap. 17) to emphasise the increase in dosage or, conversely, the use of colour contrast, simply to emphasise the diversity of dosages.

17.4 Secondary Packaging and Package Leaflet. Interferences in Use

In Chap. 17, dealing with the observations made on users, we described the most recurrent usage behaviours of the Package Leaflet: some patients immediately throw it away (literally 'get rid of it') upon opening it; others separate it from the secondary pack and put it away separately, thinking they will read it when needed; some keep it inside the secondary pack, complaining, however, that the presence of the Package Leaflet 'gets in the way' of the medicine's usage operations when it comes to taking it out and putting it back in its secondary pack.

If we try to trace the set of critical issues collected back to a few macro-categories, we observe that the Package Leaflet is weak as an information tool:

- in terms of usability (difficult to take out, open, refold, store in the pack; but also difficult to read because of the grammage of the paper, which produces visual interference between the page being read and the text contained on the remaining page, which is visible in transparency. It is also difficult to read because the folds of the paper fall over the lines of text;
- in terms of accessibility (challenging to track down the information and understand it);
- in terms of education about treatment (a considerable part devoted to side effects doesn't match with an equally important part dedicated to the benefits of taking a medicine, the support that a proper lifestyle can have in enhancing the effectiveness of the medicine; the expedients related to nutrition; and prevention).

Recently, there is a new sensitivity to the problems of information overload. Some pharmaceutical companies are supplementing the package leaflet with a card that summarises the most important information on the usability of the medicine, possible interactions with food and drink, and important warnings for the user (Fig. 17.25).

Similarly, in some medicines, information on the effects of the medicine is supplemented with advice on a correct lifestyle and diet aimed at reinforcing the logic of prevention. Below, we devote it to the Package Leaflet in its nature as an object. We do not dwell here on its usability related to the dynamics of reading: the invitation to read in a specific order; the easy traceability of the content searched for; the redundancy of information when necessary; the distinction between information destined for doctors, pharmacists, and technical personnel and that for the user; and

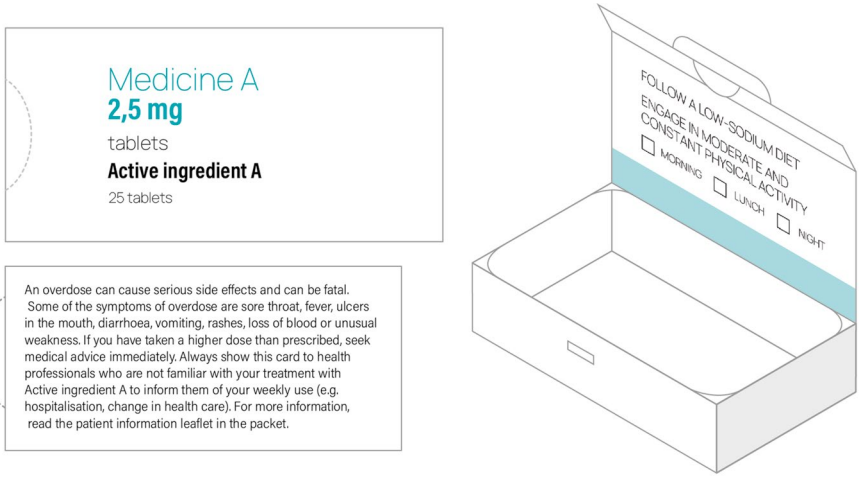

Fig. 17.25 Example of package mini-leaflets supplementing the traditional package leaflet and example of a medicine introducing information aimed at prevention

the need for linguistic forms that users can also understand. Instead, we turn here to its usability as a 'three-dimensional object' whose phenomenologies of use, beyond its communicative function, have much to do with ergonomic issues of manageability. As we have seen, the package leaflet has its placement in the medicine package, and, not necessarily, there is a close connection between its placement and the opening side. This is the case both because there is often no clear indication to the user of what the opening side should be and because there is no definitive opinion in Pharmaceutics as to whether the user, upon opening the medicine package, should find, as the first interface of the medicine, the leaflet.

There is then at least a second reflection concerning using the leaflet as an object and the multiple interactions generated between the leaflet, primary packaging, and secondary packaging.

Folded up in the packaging almost as if to wrap the blister, vial, or bottle, the Package Leaflet must be opened to 'go to work'. And, once it has performed its informational function, it is not easy to follow the folds exactly to return it to its original shape. This leads to the difficulty of reinserting the I.F. into the package and even more so of reinserting the medicine—blister or vial it may be—since interferences are created that hinder the correct repositioning of the medicine in its case.

A concluding note on medicine packaging. We have noted through observations made from the medicines most used by users, the many differing behaviours that run through the patient's experience dealing with drug treatment and the high level of interaction between the different physical and informational components that make up the drug package. We have indicated some of the more usual patient behaviours that can result from inattention, misunderstanding, and lack of basic culture about the role of medicines and their nature, but certainly in part are due to the careless design of the informational and physical features the packaging (Fig. 17.26).

Where the packaging, its shape, and the information given prove particularly ineffective is in getting the patient to perform the right sequence of steps to make the treatment effective and less risky.

We focus here on two elements that could easily be redesigned to increase their effectiveness: giving greater emphasis to visual and verbal information that educates the patient to properly dispose of the primary packaging, the secondary

Fig. 17.26 Examples of the recent introduction on the secondary packaging of medicines of complete instructions for proper disposal. Please note the text are in Italian since we're referring to the Italian context

packaging with the package leaflet, and any remaining medicine. The indications on the packaging do not have the strength to attract the user's attention. Even when they do, they risk giving the wrong information by not specifying promptly that the different components of the pharmaceutical pack must follow a separate collection process.

A second piece of information that is too weak concerns the process of reporting possible side effects, product defects, and interactions with other medicines. No user knows what procedure they should follow to report a problem that has arisen using the medicine. In this regard, it would be important for a part of the package leaflet to contain clear instructions, addressed to the patient, on how to report problems encountered in taking a medicine, or issues related to the usability of the medicine with an indication of the recipients and their contact details to whom these reports should be addressed.

We believe that the active involvement of the user in the return of the user experience can be a valuable information asset for the pharmaceutical company and the agencies responsible for regulatory activities and verification of product requirements.

References

European Parliament and of the Council (The) (2001) Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use. Off J Eur Communities 28(11):2001. Retrieved from https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32001L0083

European Parliament and of the Council (The) (2011) Directive 2011/62/EU of the European Parliament and of the Council, amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products. Off J Eur Union:74–87