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Antonella Valeria Penati *Editor*

In-Home Medication

Integrating Multidisciplinary Perspectives in Design-Driven Pharma Practices

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Integrating Multidisciplinary Perspectives in Design-Driven Pharma Practices

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Chapter 20
Pharmaceutical Packaging According to the "Packaging Ethics Charter"

Valeria Bucchetti

Abstract The chapter analyses the role that packaging plays in pharmacological products, starting with the communicative and instrumental aspects. Like and arguably more than other products, the medicine needs the prosthetic, synthetic and directing mediation aspect of packaging; the medicine is one of those types of things which, through packaging, take on a form, become products and usable content. The observations developed in the chapter take their cue from those in the Ethical Packaging Charter, a document for the study and analysis of packaging concerning the needs of the consumer, the user, the environment, and society.

20.1 The Project Intended as a Synthesis

The topic of packaging design is addressed here in its most profound sense, as a design act aimed at producing a synthesis whereby the different aspects involving the prosthetic—communicative and instrumental—dimensions of the packaging artefact are harmonised, according to the most evolved interpretation of this specific field of the project.[1] As is well known, a multitude of interventions can be ascribed to packaging design concerning specialised sectors, from those related to materials technology and its applications, to those referring to the use of more or less intelligent supports, to others that affect the structural and functional dimension, as well as those connected to dispensing devices in their various forms.[2] However, the

[1] Reference is made to packaging design as a design discipline that determines the balance between structural and communicative components and that places the semantic dimension of all the elements that make up the artefact in the foreground when carrying out the design synthesis.

[2] In this sense, to get a picture of the state of the art and its breadth, it can be useful to examine the packaging that is nominated for the competitions; the case of the *Oscar dell'Imballaggio*, organised by the Istituto Italiano Imballaggio, represents a nationwide showcase in which innovations of

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design act and its role of synthesis are capable of virtuously bringing together in a single object choice that may be asynchronous—taken over time and not always orchestrated—or ascribable to constraints or unforeseeable needs. With its directorial intervention, a design act that has the responsibility to govern a balance, to determine it even where it is absent, to compensate for gaps, and to emphasise and exalt qualities and attributes so that users can immediately interpret them. And suppose these considerations are valid for packaging. In that case, they are even more incisive for the pharmaceuticals sector because they belong to a category of indispensable products on which the person's life may depend, and because they belong to that type of objects that, through packaging, become usable products and contents (Bucchetti 1999, 2005; Volli 2001); indeed, the medicine falls into that category which requires a prosthetic mediation.

We can thus argue that the medicine shapes itself through packaging. Sometimes it assumes its own shape, when the package is what allows granules, liquids, creams, ointments, etc., to take on an identity, in others to guarantee the manageability that enables its use (Anceschi and Bucchetti 1998), to the point of becoming, more generally, a unit of measurement of its contents (a vial of…, a sachet of…). And if these considerations refer to its function as an instrumental prosthesis, transversal to the medicine category, it is different as regards the role of communicative prosthesis performed by it. Indeed, we know the approaching extent, with specific perspectives depending on the type of medicine: hospital, ethical, or over-the-counter medicines. These product categories present three levels of communicative needs, determined first and foremost by distribution logic and channels. Where distribution and regulatory criteria refer to sales, and the processes of liberalisation place the user-consumer behind the so-called free service, and a shelf offer based on communication strategies typical of mass consumption products, which transfer onto pharmaceutical packaging, the design knowledge and appellative techniques deriving from the market experience sedimented over a century of history of commercial communication.

However, as is well known, the communicative function also performs other tasks by reversing priorities. It occurs when it supports and facilitates the product-recipient relationship during the informative and preventive phases of orientation, access to administration, and, more generally, in-depth knowledge. In developing these observations, a contribution to the theme can be fostered by a re-reading of the Packaging Ethics Chart.[3] This document was drawn up to open a shared path of reflection, helpful to promote evolution of the sector, a record that through its principles, allows us to re-examine the field under study in respect of the needs of the consumer, the user, the environment, and society.

The Charter declares itself to be:

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a specific type emerge, which frequently concern the functionality of the artefact, and detailed technical aspects, which define the performance increase.

[3] *The Packaging Ethics Chart* has been drafted by Giovanni Baule and Valeria Bucchetti; it is a project by Baule and Bucchetti, Department of Design, Politecnico di Milano with Guidotti and Lavorini, Edizioni Dativo; promoted by Edizioni Dativo; sponsored by Istituto Italiano Imballaggio.

> A document of principles to be shared to accompany packaging towards a more conscious future. The Packaging Ethics Chart stands as a tool for a "system culture": it aims to bind obligations and rights that can join production with use and consumption, individuals who are bearers of obligations and individuals who benefit from rights and expectations. The Packaging Ethics Chart connects rights, principles, and values to secure an ideal agreement between the system players so that they undertake to share principles to aim at without overlapping themselves with the regulations while making this choice public.

Therefore, the ten principles set out in the charter become keys to a review. Each principle recalls a function: it is a matter of considering each individual item as part of a whole, of a bundle of processes that act intersecting and that, depending on the primary design objective and the peculiarities of the product-content, are reconfigured from a systemic dimension.

20.2 Responsible

This is the first key term proposed by the document, intended to recall a primary principle, transversal to project action and the need to consider for each project move, beyond the fulfilment of a necessity, the effects it may have. We wish to emphasise an extended responsibility that all the actors must share in the system. A responsibility that must invest the entire community and which allows us to speak of the social responsibility of packaging.

On the design side, "designing packaging involves the analysis of its instrumental functions closely linked to the communicative functions of medium and interface with the user".[4] When we consider the pharmaceutical sector, we find ourselves in a field in which design competencies often belong to distinct groups; in which the design of the various functions (instrumental and communicative) is separate, in which the role of protecting the content and its forms of delivery requires a high technological component, therefore elaborated in technical-engineering research and development contexts, within an overall design process that separates phases and competences. Thus, the notion underlying this first principle emphasises the need to merge what the design process divides by entrusting it to the figure of a designer, who takes full responsibility for the directing role at the centre of which is the user.

20.3 Balanced

This is a principle related to the value of the *right balance*.

Packaging for pharmaceuticals is inalienable, so its presence and function is certainly not in question, as is the case for other sectors. Still, it should also deal with

[4] Direct reference is made to the principle of the Packaging Ethics Chart defined as responsible.

this principle, responding to the "just enough and just what is needed" paradigm. As the Charter states: "Balanced is the packaging when it is conceived and designed with a right relationship with the content and is the result of what is necessary for its correct diffusion". Hence, the packaging must be calibrated depending on the type of medicine, whether or not it is a so-called "life-saving" medicine or the organoleptic qualities and preservation of the composition.

According to this principle, technologies that load packaging with 'intelligence', for example, can be re-examined based on a balanced choice between the service offered and its necessity, but also issues more commonly labelled *overpackaging*.[5]

And if some solutions attributable to overpackaging, at first glance, should be viewed favourably as playing the role of instrumental prostheses, in which an essential service function prevails (e.g. in the forms of dispensing that allow therapy to be managed and normalized in the conduct of daily life thanks to the device), it is instead helpful to point out how often overpackaging manifests itself due to a general principle of standardisation in packaging and optimisation of dedicated machines, leading to an imbalance between content and container. Among the most apparent examples are cases where blisters are only partially filled (they contain six capsules while providing space for up to eight alveoli, etc.) to maintain format modularity for sale without modifying the packaging line. This choice optimises processes and formats (from the size of the carton to that of the shipping packaging). Still, it has an inconsistent and unbalanced impact on volumes and quantity compared to the actual content. Conversely, as a case study, it is worth mentioning the packaging solutions that leave their parallelepiped shape (cardboard box packaging) to reduce their volume in the upper part of the pack by the medicine's behaviour, meaning that the granular product contained in the vertically arranged single-dose flow packs is deposited at the base, thus leaving a significant void in the upper part of the packaging.

20.4 Safe

Safety is a crucial principle for pharmaceutical packaging. This principle interprets at the highest level that a trust contract is implicitly established, on the level of the relationship, whenever a product is trusted.

> Safe is the packaging that gives an account of its traceability, of the processes of its production chain; it is safe as regards the protection of its contents and its hygiene, safe during transport and use. And this for the entire life span of the packaging.[6]

Thus, packaging proposes itself as a device capable of transferring through its presence the necessary guarantees that the user demands or simply expects, precisely because it recognises its role, regarding conformity, adequacy, and compliance with

[5] On this topic, see: Bucchetti (2005), Badalucco (2011).

[6] Direct reference is made to the principle of the Packaging Ethics Chart defined as Safe.

regulations. In the case of European regulations,[7] all pharmaceutical products sold in Europe must be contained in packaging with safety features that allow their integrity to be verified. In this sense, we can refer to the various anti-tampering systems to make possible forms of tampering evident. Tamper Evident solutions whose closure is armed when the product is packaged and when the seal is broken the first time it is opened, a significant part of the carton changes shape and colour, giving irreversible evidence that it has been opened. In this case, we are talking about solutions that can be perceived by touch and whose usability is guaranteed even by visually impaired or blind users. Devices for intelligent packaging, such as Time Temperature Indicators, control these parameters through integrated sensors when the contents require compliance with the cold chain.

The safety issue cannot fail to consider the different profiles of users, particularly their temporary or permanent frailties, whether they are 'passive' users, meaning coerced or obliged to take. But also, of the seriousness and repercussions that, in many cases, the error brings with it, making the term 'safe' take on an absolute centrality for the packaging of the medicine, also because of the harmfulness that erroneous actions can produce on the subject.

It is also essential to relate another aspect to this principle, namely that about perceived safety, which involves the emotional dimension of the recipients and passes through plastic and symbolic attributes of the device, which can contribute to reinforcing or undermining the user's serenity.

Psychology of colour and shape play, in this sense, their role in constructing reassurance. For example, the case of a pre-filled device for injecting the medicine whose dark red plunger, as the colourless liquid is injected, flows taking its place and, precisely because of its red colour, triggers an association, albeit irrational, with blood, developing a consequent sensation of discomfort that is repeated with each administration. Indeed, the device does not technically compromise the administration. Still, its design seems not to have considered the emotional aspects of the human beings involved and the emotional activating role played by the instrument.

20.5 Accessible

Packaging is accessible when it is easy and intuitive to use and thus takes into account every consumer's right to approach, understand and use a product.

The notion of accessibility has multiple implications as it can relate to different dimensions of the artefact. It has to do with the idea of a threshold, understood as the space of passage that leads to the objective, which makes concrete the possibility and the right to access the medicine and to carry out the administration, with the course that decrees the outcome, the quality of which can change the sign of the

[7] See regulation 2011/62/EU, which stipulates that, as of 2019, all pharmaceutical products sold in Europe must be contained in cartons equipped with security features to verify their integrity.

entire act: connoting it positively or nullifying its effects. Designing accessibility means adhering to functional ethics (Fabris 2021), linked to the model of use and ease of use, guaranteeing efficiency and effectiveness to the packaging artefact. But accessibility also implies the hostile element, the barrier; it is paradoxically affirmed where it is lacking. In its resolved form, it does not manifest itself; it only becomes evident when faced with an absence or a lack. When the interaction occurs correctly and without obstacles, the device presents itself as an interface that measures the users who do not perceive its mediation, which feels as soon as they perceive a difficulty. For example, when it fails to act on a so-called child-proof closure, or as in the case of syrup packaged in "spoon" mono-doses whose shape and size are not consistent with the force that must be exerted to remove the film that seals it, producing a consequent leakage and dispersion of the medicine, or when it must load an inhaler whose instructions declare an unforeseen complexity, but also when the traceability, perceptibility or comprehensibility of the information is lacking (Ciravegna 2010; Bucchetti and Ciravegna 2014; Steffan 2014). In its more inclusive meaning of "for all", accessibility is also guaranteed by the sensory modalities of sight and touch and involves haptic perception (Riccò 2008). The packaging can be perceived as a three-dimensional object: grasped, lifted, and handled, including tactile perception (the object is touched) and kinaesthetic perception (muscular sensitivity, perception of the position of one's limbs and movement concerning the object, for example, the weight/transport ratio).[8] Modalities that guide the recipient's actions in accessing the product and that, together with the morphological properties of the structure, graphic solutions and surface finishes, favour the identification on the packaging of the different functions (opening, dispensing, etc.). A system of access to medicine that must take into account conventions, experiences, and customs; of an introjected know-how that must be able to be evaluated each time a new form of interface is introduced, to a perspective of the economy of access, to the cognitive effort required, easy to understand regardless of the experiences, knowledge or skills of the users or their level of attention, and regardless of the conditions of the context.

20.6 Transparent

The value of transparency is metaphorical. Transparent is a postural attribute, metaphorically speaking, which concerns the chosen communicative register, through which the packaging declares that it wants to address the user directly, without

[8] See, in this regard, Bucchetti (2007) (ed.), *Packaging tra vista e tatto* [*Packaging between sight and touch*]. See also, in the same vol., Riccò, Congruenze sinestesiche [Synesthetic congruences] (pp. 15–17). See also Calabi (2007). Percezioni aptiche e cromatiche [Haptic and chromatic perceptions], (pp. 97–147) in Bucchetti (ed.). (2007). *Culture visive. Contributi per il design della comunicazione.* [*Visual Cultures Contributions for communication design*].

mystery. This means designing to develop a relationship of trust with the recipient, a primary condition, as is well-known in the pharmaceuticals sector.

Therefore, transparent packaging tends to have a low error risk and induces virtuous behaviour. As an example, the solutions frequently adopted for medicines intended for asthma treatment are inhalers that display how many doses of medicine are left. Each time the lid is opened, the dose counter counts down, and when less than ten doses remain, the area turns partially red as an alert. It turns completely red after the last dose has been used.

A further form of transparency can be recognised when the packaging directly expresses some of its properties through certain communicative moves; for example, through the rationalisation of information on the primary area of the pack. In this case, the intention is to make communication immediate through the organisation of the graphic elements according to a signposting-type perspective[9] using images that can be immediately traced back to the disease or disorder, to the anatomical elements or organs involved, which play the role of writing in pictures. An example of this is the search for standardisation of pictogrammatic systems to make the pharmaceutical form (tablets, capsules, suppositories, etc.) immediate, and that aimed at raising the quality of typographical elements concerning the choice of font (highly readable and composed according to criteria that favour reading) and its composition (line spacing, alignments, etc.) guarantee immediate communication.[10]

20.7 Informative

"It is the packaging that ensures the best information, both useful and necessary". Packaging is a pivotal information interface connecting us with the product. In the case of pharmaceuticals, this information function is performed not only by the

[9] One example among many is the project realised by settepuntoquattro: the Joint Pain, Sore Muscles, Migraine product line presents a graphic layout in which illustrations, pictograms of the pharmaceutical form, typographic elements and colour codes are designed to provide information directly on the primary area with signposting functions, useful for an initial orientation. (https://www.settepuntoquattro.it/boxes/).

Also, because of both the package leaflet and the outer packaging—according to legislative decree 219/2006—may contain graphic elements aimed at making certain information useful to the patient more explicit and comprehensible, to the exclusion of any element of a promotional nature (Art. 79). The use of pictures, pictograms and other symbols must serve to clarify or highlight certain aspects of the text and not to replace the text, as indicated by AIFA provided that the signs used are widely understood and are not misleading.

[10] In the field of Pharmaceutical Packaging Design, see the research subject of Master's degree theses, in particular: "The visual communication of the medicine in the critical area", thesis by Gloria Angelini, supervisor Gianluigi Pescolderung, co-rapporteur Elisa Pasqual, IUAV, academic year 2012–2013; and "Undesirable effects. On the communicative accessibility of pharmaceutical packaging, research and design', by Agnese Rodriquez, supervisor Valeria Bucchetti, Master's Degree Course in Communication Design, Politecnico di Milano, academic year 2010–2011.

packaging but also by complementary devices, such as the leaflets, integrated with it. Information that develops today in a communicative context reshaped starting from the technological-digital transformation, characterised by an overall process of democratisation of information and determined by the apparent ease in the availability of data and news[11] and by the diffusion of tools for accessing the web, and consequently information. Changes modify the relationship between those who hold the knowledge and those who use it. But, when we refer to the information functions of packaging, we touch, in the case of pharmaceuticals, on a further issue since we face products with a high density of information content that cannot be unequivocally hierarchised. On the one hand, a large amount of information is available and, on the other, the criteria by which it is organised. This is an imposing design task for which the medical, pharmacological and regulatory reasons, with their associated need for precise expressions conveyed through technical-scientific language, are flanked by the need for comprehension on the part of a heterogeneous user base in terms of literacy, but also driven by a wide range of motivations and multiple emotional profiles that, as we know, characterise patients. Indeed, information may be sought to obtain reassurance or for reasons attributable to mistrust, to check or compare, to inform oneself and act consciously in the case of self-administration, for prudence and to protect oneself from possible incompatibilities; but also based on other motivations that have repercussions on criteria of interpretation of the corpus of information, which are highly subjective.

Today, the informational capacity of pharmaceutical packaging expands through the implementation of an *active interaction surface*[12] that transforms labels into interfaces that provide alerts and transfer information,[13] but also through the enhancement of the dialogue between communicative devices, interconnecting with other devices, delegating to them what in the past was the prerogative of the package leaflets, according to a cross-media logic that goes beyond the written surface of the packaging. Today's information dimension is made possible by smart packaging solutions capable of communicating with smartphones, tablets, PCs, etc., thanks to the evolution of digital channels, from smart labelling technologies such as Rfid tags, Nfc or QR codes that can be linked to websites and web pages, to minisites, to PDF documents, as well as to stand-alone videos, or connect to apps, thus extending the communication capabilities of the leaflet (for example by making information in different languages immediately available) and the fruition times that follow the

[11] A transformation that brings with it contradictory aspects since the availability of an extremely large amount of information is not matched by useful cultural tools to make a selection from the sources and disciplinary knowledge to understand them.

[12] It is interesting to recall some exploratory projects carried out in the early 2000s, in which packaging was proposed as an active interaction surface on which information could be displayed, contextualised in real time according to user input. This hypothesis was based on the use of polymer semiconductors that made it possible to transform the casing into a matrix of pixels that could be illuminated when needed. See, in this regard, Capitini (2004), pp. 143–151.

[13] Reference is made, for example, to the experiments of the start-up Inuru and the ELFI labels tested to help patients avoid mistakes when taking medication through visible light warnings on the label itself. See https://www.inuru.com/solutions/medical (accessed 17 January 2023).

parameters and dictates of digital communication. This extension of the information function is also achieved using intelligent packaging systems involving, for example, cartons made by printing conductive inks using flexographic technologies, which make it possible to connect with smartphones, as well as cartons equipped with a screen and sensors designed to support patients in monitoring and adhering to therapy.[14]

20.8 Up-to-Date

The ability to constantly relate to the society whose values it represents is a principle that distinguishes packaging and its qualities. Like any designed artefact, it also reflects the culture that determines it and, in turn, contributes to creating it. This happens regardless of the degree of awareness of the designer and the user who interprets or assimilates its values, even when these go unnoticed. The quest to be contemporary has, over time, led to a continuous evolution of pharmaceutical packaging and has determined its transformations.

From the changes that have involved formats, now articulated in a range of declinations (from the reduced ones, for example, with the revival of the *sachet of Minerva* model), to the innovation of devices according to a perspective of improved interaction and greater ease of use, from those intended for the safety of the packaging and its opening systems to the design of diversified devices concerning the functional requirements of administration, suffice it to think of the diversity of devices that contemplate the packaging in its role as an instrumental prosthesis, as a medium for dispensing; think, for example, of the variety of injectors or packaging-tools designed to allow delocalised medicine intake (and hence without the need for additional instruments such as spoons, syringes, etc.): single-dose packaging, flasks, etc.): single-dose packaging, bottles with applicators, single-dose applicators, prefilled pens, etc. But let us also think of the set of collateral devices, often complementary, as in the case of the blister-holders designed to facilitate the storage, during everyday life, of tablets or tablets and to prevent the blister from deteriorating if transported over a long period, for example in a bag, with a consequent waste of the medicine it contains. These examples restore the adherence, though certainly still perfectible, of packaging to the *esprit du temps*.

[14] See what was developed with the PhutureMed project https://www.packagingstrategies.com/articles/88367-palladio-group-and-e-ink-introduce-phutureMed-advanced-packaging-solution--for-pharmaceutical-products (accessed 22 December 2022).

20.9 Forward-Looking

While packaging must fully respond to the *here and now*, it must also be able to place itself *in a correct relationship with its future*. It must respect the prefigurative principle of design, the ability to give shape to solutions not only based on an immediate advantage or adhering to an existing model, but it must be able to develop new scenarios and foresee spin-offs and consequences.

The Charter recalls that:

> Forward-looking packaging is capable of grasping changes in advance, fostering new consumption models, and evolving behaviours over time. It knows, therefore, that it must modify itself over time: it must experiment on itself to favour its future transformations. Packaging must be able to embrace all necessary changes: it must be the subject of research and forms of experimentation that make it evolve; it must have tools that enable it to foresee its transformations. Packaging must involve a constant commitment to research and innovation. As consumers, we thus know that we face an object that knows how to rethink itself for tomorrow's users.

Packaging, in its evolutionary process, reacts by facing new challenges and responds to changing habits and lifestyles, just as it cannot fail to take into account, with due anticipation, for example, the demographic transformations of the population, falling into scenarios in which the repercussions on the service functions of packaging are correlated to the increase in chronic pathologies and, consequently, to the rise in regular consumption of medicines.

But this forward-looking principle must also involve communication functions and their change, in line with the evolution of communication formats and society's digitalisation level. There are many studies, experiments, and examples. Regarding the enhancement of packaging functions to support adherence to the therapeutic plan, pharmaceutical packaging expands its information functions through a directorial orchestration of several mediums, according to a cross-media perspective.[15]

Once again, the most relevant examples concern the interaction of packaging (in many cases the case) with devices such as smartphones to monitor the correct intake of the medicine[16] to remind patients of their intake, record the date and time each tablet was taken from the packet and the position of each tablet or pill when removed from the wrapper.[17] Even extending its action by activating a dialogue, for example, with the "electronic diary" of medicines, designing an increasingly targeted

[15] Concerning the relationship between demographic and digital transformation, see what emerges from the research work carried out by the Università Cattolica del Sacro Cuore in Milan, a member of the 'Harvest European Project', among the winners of the European call for proposals 'Ageing and Place in a digitising world', launched by the More Years Better Lives joint programming initiative. https://www.repubblica.it/tecnologia/2018/01/30/news/italia_solo_1_anziano_su_4_usa_smartphone_e_pc-187659487/

[16] One example is Phill Solution by the Palladio Group.

[17] See:https://www.worldofprint.com/2011/02/16/stora-enso-pharma-ddsi-wireless-a-new-medical-package-offering-improved-opportunities-for-real-time-adherence-control/ (accessed 27 August 2022). See also the Cerepack project, resulting from a partnership between MWV and Cypack.

interaction in which acoustic signals, or reminders through text messages, constitute additional functionalities underpinning clinical trials aimed at integrating and increasing the service.[18]

20.10 Educative

The educative function can be traced back to an ontological principle of pharmaceutical packaging.

If every prosthetic object, and packaging among them, has in itself an educative component that has to do with how the object transfers indications through the programme of actions it contains, that is, it has inscribed in itself—in its form, in its components, in its very structural orientation—, the actions that the user is going to perform, the packaging of the medicine must interpret this component most profoundly.

Its educative function must be exercised to direct behaviour towards correct administration (respect for the therapeutic plan remains one of the nodal issues), which frequently passes through adequate interaction with the artefact, where this involves loading, assembling or, more simply, referring to the opening/closing of the package. In particular, the educative function, in the sense of a function designed to develop and refine practice through exercise, assumes a real centrality in terms of interaction whenever a new solution is introduced with which the user is unfamiliar, namely when it must accompany the user in a training path enabling use. A small example of this is the single-dose drops which, after separating the single unit from the stick that welds them together in series, require the user to act on the seal of the single opening and turn it upside down to allow it to take on the function of a re-sealable 'cap': an elementary but not immediately intuitive gesture.

More generally, the educative function must be extended up to the moment of disposal and, therefore, as is the case for the entire packaging sector, the packaging itself must provide the necessary indications in compliance with regulations, but also promote, through an appropriate design of the communicative elements, attentive and responsible behaviour. One thinks of the disposal of the packaging and, in some cases, of the packaged medicine, and of the need to promote and improve, through design action, the instructions of a prescriptive nature, the behaviour relating to the correct disposal of the product during the separate collection at home (what do I separate? where can I throw it?) or at the collection points in pharmacies (do I only dispose of the tablets or do I throw them without taking them out of the blister pack?).

[18] These are experiments that draw scenarios and models according to new paradigms. The data can be quickly downloaded into a computer for analysis by the patient or healthcare professional.

20.11 Sustainable

As is known, the sustainability of packaging concerns the materials used, the resources, and the forms of optimisation of processes and transport, according to the guidelines referring to the environmental sustainability criteria indicated by the PEF[19]—The Product Environmental Footprint—, includes multi-criteria measures of environmental performance throughout the life cycle of the packaging produced with the general aim of reducing environmental impacts taking into account the supply chain.[20] In this perspective, one essential reading focuses on a specific issue, namely the various forms of waste involving pharmaceuticals and, together with them, the packaging that carries them.

On the one hand, it refers to the shortcomings of the packaging or its weaknesses. For example, one thinks of what happens with bottles equipped with a dropper pipette when the inadequate length of the cannula prevents the entire quantity of medicine contained in the bottle from being used, not allowing the residual medication deposited at the bottom to be taken up. A waste of seemingly insignificant proportions that is only fully perceived when referring to constant administration over time. On the other hand, examples of the opposite sign: this is the case of those packages that, through the introduction of technologically advanced devices, allow the dispensing of calibrated and sterile drops, thanks to the presence of a filtering membrane that prevents bacterial contamination. A solution that, thanks to a guarantee of sterility, extends the duration of use after opening, thus allowing the entire content to be used, and thus representing a sustainable alternative to single-dose dispensers.

Regarding this issue, it is worth recalling a further question that concerns the function and role that packaging has, and can have, in combating medicine wastage, namely the forms of wastage that are most closely related to personal behaviour for which it would be interesting to address the political and financial reasons and interests that have so far prevented corrective action. This is a mighty phenomenon: eight billion tablets go unused every year in our country, or 30% of the 24 billion doses of medicine that Italian hospitals or citizens buy yearly: an enormous waste because of the expiry date.[21]

On the one hand, this phenomenon concerns the overall system and its digitalisation, the hospital's digitalised and customised distribution of medicines, and the way they are administered. On the other hand, it opens up spaces for design research

[19] See: https://ec.europa.eu/environment/eussd/pdf/footprint/PEF%20methodology%20final%20draft.pdf

[20] See what has been published, albeit referring to the food sector, by De Giorgi in Sustainable Packaging? A multi-criteria method for evaluating food packaging.

[21] See the statement by Carlo Gaudio, Aifa board member and director of the Department of Cardiovascular and Respiratory Sciences at Sapienza University in Rome. https://www.ordinefarmacistiroma.it/gaudio-aifa-medicinali-scaduti-spreco-da-8-miliardi/ (accessed 27 August 2022).

into the flexibility of formats, directing the study towards customised packages, since an incorrectly 'sized' package leads, as is well known, to waste.[22]

The path of a double expiry date on medicine boxes proposed by Carlo Gaudio[23] should also be read in this direction. In addition to the classic expiry date (shown in black), a second expiry date in red is hypothesised that could highlight the last months of validity.[24] A sort of *last months notice* that would help people realise that they have products that are about to expire and that, if they are no longer needed because the therapy has ended, they could be returned to municipal pharmacies or handed over to non-profit organisations that distribute medicines free of charge to people in difficulty. Medicines that are unused in their last months of validity could, in this way, be made available—ensuring the transparency of their pathway—to guarantee those 'free treatments to the indigent' envisaged by the constitutional dictate.

20.12 Principles of Design for Accessibility

What has just been outlined, with the help of the principles of the Packaging Ethics Chart, is a framework that can play an instructive role in packaging design processes for pharmaceutical products from a perspective that places at the centre, in addition to its role as an instrumental prosthesis, that of the interface, mediating device, and communicative artefact that directs behaviour, translates, and provides information. Today, packaging cannot fail to be conceived in a systemic key and, therefore, starting from the artefactual system (Bucchetti 1999; Badalucco 2011), requiring a direction capable of harmonising processes, considering instances that move from needs that are sometimes opposite, reconfiguring, if necessary, technical and technological innovations so that users remain at the centre. Thus, an area is emerging that continues to offer a field of research of particular interest (Pareek et al. 2014) and which brings to the forefront nodal themes for design, and for communication design in particular, which have their focus in the *design of accessibility* (Baule 2011; Bucchetti and Ciravegna 2014), since it is only with this form of designed mediation, of the interface in the extended sense, that the user enters into a relationship. It is on the quality of this interaction that the success of the internal process and the chain of choices that nourished it depends, or, on the contrary, its frustration. It is an area of design that requires a specific competence, a highly specialised *packaging designer* figure capable of orchestrating all the points dealt with by the Packaging Ethics Chart and knowing how to govern them in design through coherent declinations.

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[22] On these issues see: Manifesto per la Sostenibilità Consumeristica, promoted by Federfarma.

[23] See Carlo Gaudio.

[24] Regarding expiry dates, the research work carried out within the food sector for the Ministry of Economic Development to provide improved tools for the design and use of expiry dates remains of interest. Research published in: Bucchetti and Ciravegna (2007).

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