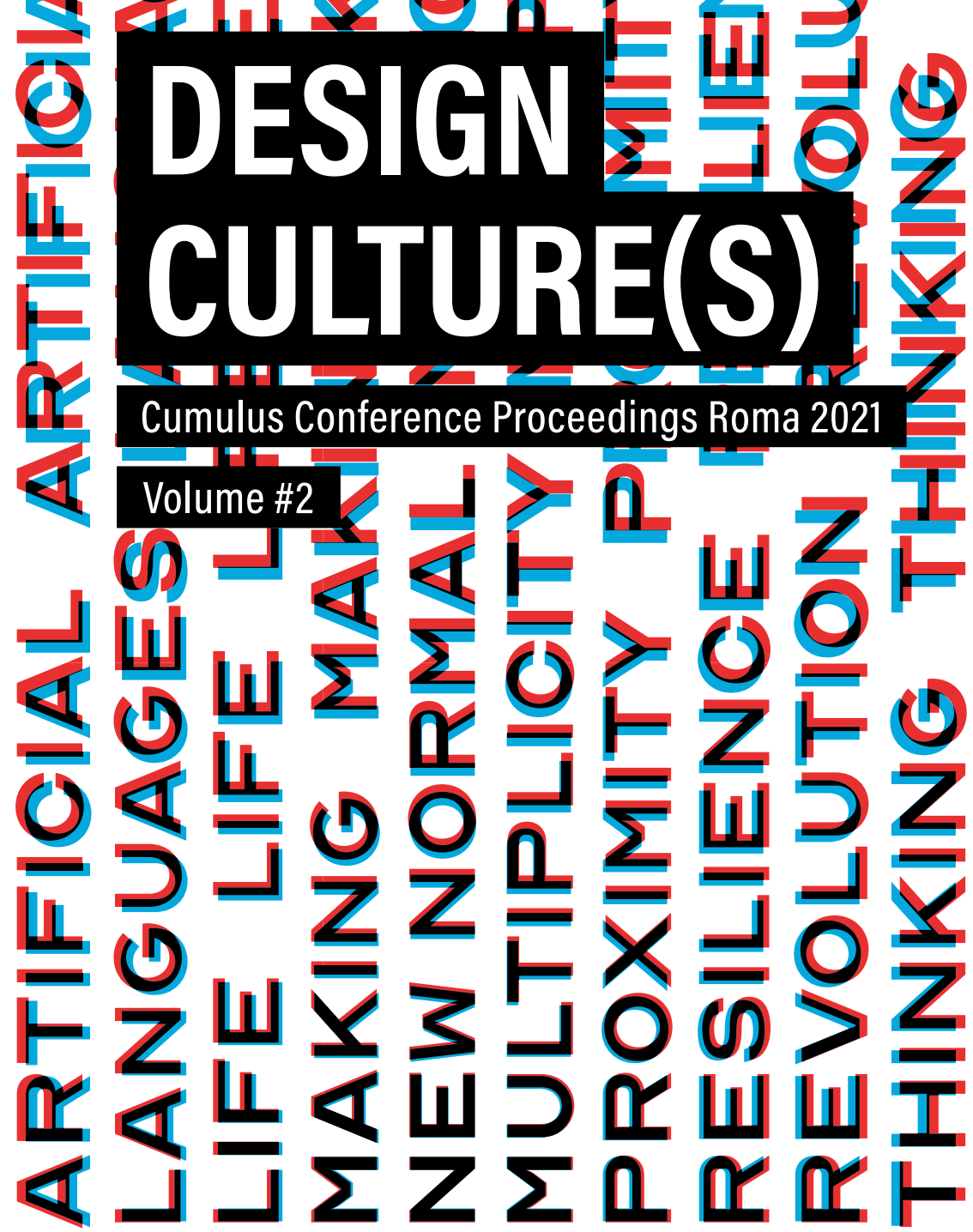

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DESIGN CULTURE(S)

ROMA 2021

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Post-pandemic medicines: towards a new normality

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Abstract | The Covid-19 Pandemic has caused two types of phenomena: on one hand, it has profoundly changed people's lives, calling into question even the most normal behaviours, such as being able to walk out of the house; on the other, it has accelerated the consolidation of new habits, not necessarily appropriate. This is the case of behaviours linked to the dimension of care, of self-diagnosis and the consequent self-care are approaches amplified by the ongoing pandemic, bringing to light the lack of an overall vision of the Italian care system and in particular of the medicine management.
This paper explores this issue, firstly offering an overview of the problems and the changes taking place, and then offering some potential openings on project ideas. These openings would rethink the future processes of homecare and the entire drug supply chain, from production to distribution, up to post-sale tracking and consumption, to the disposal.

KEYWORDS | POST-PANDEMIC MEDICINES, MEDICINES AND TRACEABILITY, MEDICINES AND SMART TECHNOLOGIES, 3D PRINTING DRUGS, PERVASIVE AND PERSONALISED CARE

1. Pandemic distances: new behaviours in care

Indeed, the ongoing Covid-19 pandemic is radically changing many of the behaviours that take place in our daily lives. Old practices that have always characterized our ordinary life, are giving way to new experiences that are likely to normalize early, even if offspring of discomfort and behavioural restrictions (Van Bavel et al., 2020).

Distance, fear of relationships, isolation are the main drivers of new behaviours, affecting the relationship between doctor and patient, patient and hospital facilities, patient and disease, patient and care (European Union, 2020).

In an attempt to reduce the risk of contagion, many health services have drastically reduced outpatient visits and hospital admissions, revealing the weakness of the health system that, in recent years, especially in Italy, has followed models of strong centralization at the expense of a territorial medicine (Armocida, 2020; Dell'Acqua, 2020).

Like all disruptive events, the pandemic is proving to be a powerful catalyst for system innovations. An accelerator of innovations already in place, such as e-health and all forms of digitization of therapy that could, shortly, make available new modes of remote prevention, treatment, and care (Fagherazzi, 2020; Cobelli, 2020). The new ergonomics and proxemics of distance (Bolzan et al., 2020) generate new behaviours and processes and, at the healthcare level, affect the care system at different scales, from the places designated for this purpose to the individual drug packages. It is on this last aspect that this contribution dwells, probing the different aspects of pharmacological care put on the test bench by the current pandemic.

2. “Living” and “Orphan” medicines

The Covid-19 Pandemic shed light on the lack of a strategic vision of healthcare as a system. We can view the pandemic state as an amplifier of many issues related to the healthcare system as a whole and traditional care practices (Armocida, 2020). Epidemiologists and immunologists are predicting upcoming pandemics as a normal condition of our future. Viruses and bacteria will occupy a decisive place in spurring the opening of new diagnostic and therapeutic avenues. It is projected that by 2050, 50 million people will die from bacterial multi-resistance (Turin, 2018). The most traditional antibiotics and antivirals have drastically reduced their effectiveness in treatment (Li, 2014), partly due to their overuse in therapies (Alhomoud et al., 2017) and indiscriminate release into the environment, through crops and farms.

New therapies are appearing on the pharmacological research front. In Europe, the first clinical trials are starting to evaluate new forms of treatment against infections. These are trials already in use in the countries of the former Soviet Union (Altamirano & Barr, 2019) based on substances of a biological nature. They are called “phage cures” because they are

based on selective viruses whose peculiarity is to feed on bacteria: those that traditional antibiotics are no longer able to attack due to the resistance acquired by these microorganisms. These phage substances are “alive” and precisely for this status, their use poses new questions to science (on the risks implicit in therapeutic uses), to jurisprudence (on the rules of use of biological material very different from drugs whose peculiarity is to have a stable active ingredient) (Verbeken et al., 2017; Huys et al., 2013). But also design, as a translator of matter into objects, into production systems, into sales systems, into packaging, storage, and transport processes may play an important role in "shaping" this new system of care, through solutions designed starting from the needs gathered from the observation of user behaviour (Stegemann et al., 2016).

The transition from the experimental and laboratory level to the large-scale production of such peculiar products challenges the project in all the relations - widely explored - that link the term design to the industrial one, as well as challenging it in relations not yet fully addressed, such as those that connect the project to the transformations of the biological world and living matter (Weiner et al., 2000). It also activates systemic reflections on the role that the design approach could have in the field of pharmaceutical products in general. The pharmaceutical sector is a context which, despite huge investments in R&D that have historically led to innovation among the most advanced, has not paid systematic attention to the evolution of pharmaceutical shapes in order to improve the assumption and facilitate the processes of interaction with the patient. Furthermore, in the pharmaceutical sector, industrialization processes are based on rigorous criteria in terms of quality control, safety, efficacy, and economics. These plans are often in contradiction with each other and push, as in the case of some types of medicines for limited use, such as the "orphan drugs" - so named because they are intended for rare diseases, often "orphan" of the drug - to go to small production lots, almost artisanal in nature or, to quote Maldonado, super-industrial (Maldonado, 1976). Orphans, even more so, in the pandemic era when all industrial efforts have been diverted - sometimes with reconversion processes - towards the production of medicines and sanitizers of wider use.

“Living" and "orphan" drugs are two examples of the compelling relationships between the form of medicine, the form of the industrial process, the logic, and economies of production. To these tight logics are added the standards that define formats and sales packages according to standards aimed at responding to product safety and quality criteria (Van Baelen et al., 2017). These standards (which impose, for example, the minimum number of doses per package) are binding in Italy as well as in many European countries and, if on the one hand, they are effective in guaranteeing the safety and integrity of the product, on the other hand, they do not allow to meet the needs of personalized therapies for patients (Minghetti et al., 2014). There is also a lack of a design approach aimed at simplifying the experience of using the medicine, starting from the way in which the information for use is presented to the form of the packaging; the design process is very often unbalanced in favor of the reasons of production.

There are some virtuous examples, both currently on the market, such as some blister packs of contraceptive pills, and in the development phase, as in the case of the FebriSol project (www.febrisol.com); in both examples, elements and affordances have been designed that encourage the processes of interaction and consumption of the drug. Actually, in both these cases, information is presented on the primary and secondary packaging, guiding the user to the consumption of the drug and - thanks to physical interaction, such as crushing the blister or scratching the label surface - communicating and reminding the daily intake of the pill.

In the United States, drugs are sold according to the duration of therapy, and contained in prescription bottles; these containers are indistinguishable from each other and might cause poor adherence to therapy or errors in the use and consumption of drugs. If on the one hand, the process of care and therapy is personalized, on the other hand, the experience of care and management of the drug presents significant critical issues and risks, due to an object not properly designed for interaction with the user. An example of how design can address this challenge is Deborah Adler's project for CVS Pharmacy, to redesign the package and label (Adler, 2017). Concerning the package, different ones have been designed according to the type of drug to be contained; then colored rings have been realized, to be added to the packaging as customization and to make it visually more recognizable. Regarding the label, the hierarchy of the information has been reorganized, making more visible the name of the patient, the type of drug, and the useful indications for taking the medicine.

Personalization of the drug and its wrappers, containers and blisters, and attention to the design of the interaction and user experience with the drug represent perhaps one of the most important challenges that pharma should be looking towards. Especially at a time when pandemic behaviours are proving to be powerful accelerators toward autonomous and increasingly domestic management of care.

3. 3D Printed drugs: towards personalised care and distributed production

The applications of additive manufacturing related to Health and Care are growing and, according to data from the International Data Corporation (IDC), in the Western European 3D printing market, what is driving the growth are precisely the applications in the medical field, which in 2019 accounted for about 33% of the total spending of 7.2 billion in the additive sector (Naghshineh et al., 2020). In this regard, the path paved by experiments with 3D printing of the "custom" drug (Chavda, 2015), can prove revolutionary by introducing new logics of product, production and distribution process, prescription and dispensing of the drug.

In the health sector, there is an area of convergence between the official healthcare system, the making culture - as a new way of manufacturing - and patients as bearers of innovation

through the experimentation of devices for healthcare, according to a "Do It Yourself" logic (Maffei et al. 2019); these emerging socio-technical transformations seem to go together with those medical-pharmaceutical research trends that go towards *ad personam* treatments and that now constitute a consolidated research direction. However, these scenarios cannot be transferred tout court within the context of pharmaceuticals.

Indeed, the pandemic has fostered behaviours that distort the concept of personalisation, which was already widespread, and which are now encouraged by the imposed doctor-patient distance. This distance has led many patients to self-prescribe therapies, to borrow therapies from the network or from the experience of other patients (Bessell et al., 2003; Malik et al., 2020). On the other hand, what can be transferred by the new technological practices is the centrality of the patient, who is no longer just a "human factor" but a "human actor" in innovation processes (Maffei et al. 2019). As a patient personally involved in the dynamics of pathology and its treatment, he becomes a superuser, enabled by communities of designers and systems of digital experimentation (such as Fab Labs and makerspaces) to the role of the lead user (Von Hippel, 1989). A role that makes the patient an activator and an active participant in innovation processes. In fostering the emergence of the patient-innovator, these evolved forms of user participation simultaneously activate new forms of user-oriented health care (Oliveira et al. 2015; Sienkiewicz et al. 2017).

Technology, in other words, has triggered changes in mentality and cultural attitudes that go well beyond merely its technical-productive potential. Not that they should be put in the background. Far from it. The lines of experimentation for the creation of 3D printed pills, balanced on the personal needs of each patient, follow the logic of the small-batch, useful as we have seen in the case of “living” or “orphan” drugs that struggle to find space in traditional production lines. They also go in the direction of the unitary drug that replaces, in a personalized way, the multi-drug therapy, thus obviating the frequent errors of incorrect dosages or improper dosages (Norman et al., 2017).

Such examples are: the Galeno trial, initiated by BIOlogic, in which the digitization of capsule production allowed the subdivision of the capsule into modules, making it effective for the integration of active ingredients with scheduled release schedules; a 2014-dated study, in collaboration between the University of Milan and Massachusetts Institute of Technology, on the feasibility of Fused Deposition Modeling (FDM) 3D printing in the production of capsular devices for oral pulsatile release, based on a polymeric (hydroxypropylcellulose, HPC) swelling/erodibulum (Melocchi et al., 2015); the start-up Multiply Labs (multiplylabs.com) focused on creating multidrug therapies for cardiovascular disease, diabetes, HIV, and mental illness through capsules that contain each patient's daily prescription in a single capsule, with the goal of correctly dosing the patient's medication and improving adherence to treatment; the production of FabRx (fabrx.co.uk), a British company founded at University College London, which is focused on creating personalized treatment medicines - in terms of dosage, shape, size and dose combinations - specifically designed for on-site production at pharmacies or clinical trial units.

Although these cases are still a niche and are not destined to become the "new normal" with immediacy, we would like to underline here how, personalized production, modifies the industrial logics, also in terms of their territorial distribution, favoring new proximity to the hospital, to the doctor, to the pharmacist and ultimately to the patient and his needs.

Through the development of strategies such as those mentioned, moreover, it will be more guaranteed the safe and controlled accessibility to the drug and easier to manage the tracking of the entire supply chain of the pharmaceutical product.

In this field, a customization culture has not yet reached a sufficient maturity level, similar to the one that design has brought to other goods, interpreting it in a strategic way to make it become a competitive advantage factor. In the pharmaceutical sector, the systemic customization can offer different design chances, such as: the design of shapes conceived to meet the users' challenges (e.g., prehension, swallowing, recognizability, etc.); the customization of dosages; the research of potential ways of "joining" the active ingredient with the excipients, in order to enhance its bioavailability according to defined timing; finally, the hybridization of active ingredients in a single pharmaceutical shape.

Design can and should also intervene in the communication sphere in order to prevent the spread of a misconception of the concept of personalisation, which misinterprets the potential of available technologies and which could be exacerbated by pandemic isolation.

4. The Pandemic and the counterfeit medicines

During the pandemic, the strong limitation or even abolition of traditional diagnostic practices due to the high risk of infection has encouraged forms of DIY diagnosis and treatment. The Web reveals itself as a channel not without dangers, both in the diffusion of knowledge coming often from individual experiences that assume the strength of a generalizable knowledge, and above all in the concrete dispatch of care.

It has long been shown that the online sales channel is dangerous in the purchase of drugs dispensed by circumventing the necessary prescriptive path that makes the therapy unique and individual. Phenomenon amplified by the pandemic situation with a surge in the sale of drugs for the treatment of symptoms from Covid-19 and counterfeit vaccines (Ministero della Salute, 2021; Interpol, 2021; CNBC, 2021). These have been defined, not surprisingly, the new "liquid gold" (Fregatti, 2020). The phenomenon of counterfeiting and the increase in illegal trafficking of drugs (in particular antidepressants, disinfectants, antibiotics, antivirals, as well as medical devices such as gloves, masks, gowns, diagnostic tests, etc.) has had a high point from March-April 2020 (AIFA, 2020; Gruppo di lavoro ISS Farmaci COVID-19, 2020).

In April 2020, the Istituto Superiore di Sanità published a Report on the risks of online drug purchasing, warning about DIY coronavirus treatments. (ISS, 2020; Cazzaniga & Di Giorgio, 2020). Besides, on December the 3rd, 2020, the Italian Medicines Agency (AIFA) issued a Recommendation already christened as "Enhanced Traceability Drug" to increase the power

of the European traceability standard 2011/62/EU (European Union, 2011). With this recommendation, AIFA envisages the use of a digital platform, on which pharmaceutical companies are required to upload the serial numbers of the individual packages of each pharmaceutical product, before their shipment. AIFA, in this way can follow the path of the drug both towards the hospital channel and towards pharmacies.

5. From the pandemic, the design of new opportunities

The reinforcement of serialization, aimed at combating the illicit purchase of drugs, already widely in use but widespread during the COVID pandemic, lends itself to be an opportunity to stimulate new project scenarios, precisely because it allows to follow the path of the drug up to the end user. Their introduction has produced cascading effects, some of which are necessary to optimize investments in the readjustment of production facilities, others related to a more careful observation of the drug throughout its life cycle, from production, distribution, prescription, dispensing, purchase, use and consumption, until disposal. Even after the pandemic, this observation leads to a systemic increase in design activities related to good practices in the use of pharmaceutical products aimed at sustainability, which could become the standard in medicines life cycle management.

Serialization and antitampering have been, for example, an opportunity to redesign the secondary packaging of the drug, to ensure greater clarity and ease of access to information; understanding and simplicity in use; enlargement of the user base even to the weakest groups (Baule & Bucchetti, 2015). For example, the antitampering has for the first time forced the sale of the sealed drug. In this instance, the rule, born for safety purposes, has yielded the side effect of producing an increase in unused drug waste. The seal placed on the pack does not allow the package to be inspected to verify the shape and size of the prescribed drug. It is well known that, particularly in elderly patients, the difficulty in swallowing - especially tablets - is amplified by the size, thickness and roughness of the drug's surface. During the Metadesign Course within the Product Design Bachelor’s Degree at Politecnico di Milano, several exercises carried out on drug packaging, to improve its communicative potential, have brought out the need for pharmaceutical companies to represent in 1:1 scale the shape and size of the drug contained, to support patients with swallowing problems in the right choice of purchase. Confirming the need for this information integration, on December the 10th, 2020, Teva Pharmaceutical Industries (www.tevapharm.com) announced the new company policy that includes the obligation to report on each package the representation of the content in real size at the Smart Packaging Conference. Another virtuous example of how the anti-tampering regulations are guiding companies to more comprehensive interventions on packaging, to increase the level of security, is provided by the folding boxes, tamper evident, designed and produced by IGB Bressan whose R&D Centre has worked to respond to the regulations by integrating child resistant packs.

This is the context in which new design strategies can be included to extend the medicines' tracking to cover their entire life cycle, in order to move towards a fully smart medicine.

6. The attributes of post-pandemic medicines: smart and traceable

The serialization operations, aimed at making traceability possible, are useful tools to provide patients, health services and public administrations with greater forms of protection and guarantee on the originality of products (Piutti, 2020). They are made possible by the new opportunities that digitization makes available and are a first step in a series of broader interventions aimed at the “tecnologization” of the drug and the objects that surround it, to improve its use in the different phases of its life cycle.

We tend to christen all consumer products, including pharmaceuticals, as “smart” whenever a single technological application intervenes to modify or expand the possibilities of interaction between user and product; in the case of pharmaceuticals, this is often to mitigate the many problems in the proper management of therapy. Sensors to capture data useful for patient monitoring; ultra-broadband connectivity to allow data to travel and devices and people to communicate; internet of things, biotechnology and nanotechnology for targeted treatments; use of smartphones, apps, wearable devices to monitor vital parameters; ingestible digital pills that cure only diseased cells; QR codes that expand the package insert with how to take the drug and make the information available in different languages; smart carts that can detect the correct distribution of drugs in the departments; smart bracelets that allow the health worker to automatically select the patient and his correct therapy, etc (Pozzi, 2019).

But, once again, the breadth of the aspects of drug therapy touched by the pandemic, and their process relationships, have precisely demonstrated the need for a system approach to the issue of medication and treatment.

At this stage, each pharma is moving in an autonomous mode. This modality produces a puzzle of non-organic interventions, lacking a framework within which the various innovations can unfold their potential. Just as an example, we note that serialization for traceability purposes allows for the monitoring of particular aspects of the product's life (e.g., where the drug is located along the sales channel), but leaves uncovered and at the same time suggests that the forms of drug monitoring could be extended to the disposal phase (Chaves & Decker, 2010).

Moreover, it suggests that the many forms of quality control of products, used for example in food (Chen, 2020), could be introduced with positive implications on the fairness of use (adherence) of the medicine both in home therapy and in the hospital environment. We refer for example to "smart labels". We refer for example to the "smart labels": so far, there are two types of smart labels, mainly used in mass retailers and - marginally - in the

pharmaceutical industry, namely thermo-chromic labels and the ones with integrated RFID sensors.

The first can undergo a change of color (temporary or permanent) as a result of a thermal shock or temperature change. The latter, thanks to the presence of RFID sensors and the information they contain, can be used to ensure the integrity and traceability of products, from the production cycle to the sale, providing useful information to the consumer during use and consumption (Pozzi, 2019).

In pharmaceuticals, the massive diffusion of these types of labels could certainly benefit both the production, management and quality control processes and the user's experience of care. The design and integration of smart labels and products capable of reading and displaying the information contained therein, represents a challenge for new home care and telemedicine systems and processes.

And it is also the task of design to translate and even make plausible solutions that risk remaining only chimeras in the world of medicine. Consider, for example, the possibility of remotely communicating that the drug has been taken, an issue that is anything but trivial without a complex feedback system. The actual assumption, to be detected remotely, requires sophisticated technologies, very useful even and especially in a hospital environment, especially in high-intensity infectious wards, such as departments Covid-19, where there is the impossibility of staying inside the room during the assumption of therapy by the patient.

Some technologies under development, such as sensors and electronic circuits integrated into ingestible drugs, may be more appropriate for this purpose. Thanks to their small size, they can be ingested by the patient, to have accurate images in real time of some tracts of the digestive system, or to monitor the health status of people, or to control the correct adherence in drug treatment (e.g., PillCam, Proteus Digital Health, Abilify Mycite).

And extended or enhanced traceability could complete the life cycle of the drug also in the hospital environment where all steps, from the prescription, to the supply at the hospital pharmacy, to the storage of drugs in the ward cupboard, to the preparation of the therapy trolley, up to the patient's bed, are steps of a complex process with a high possibility of error because highly dependent on the operator. The introduction of drug and patient identification codes, already widely used in several European countries, has proved very useful to reduce errors in administration (European Directorate for the Quality of Medicines and Healthcare, 2018).

Finally, the management of the drug when it becomes waste, for different reasons such as its expiration, discontinuation or change of therapy, is not yet so structured and controlled, in the same way as the disposal of other types of waste (Žiauberytė, 2011). Indeed, to date, many drugs are thrown in the common waste, becoming a risk to public health and the environment (Li, 2014; Vatovec et al., 2017). Thus, the drug could be tracked not only in the production, transportation, purchase and intake phases, but also in the disposal phase, both

in terms of product design (e.g., baskets) and service design (e.g., the role of the pharmacy in collection procedures). While from a cultural point of view it would be necessary to further sensitize and educate citizens on the proper disposal of medicines, on the other hand, thanks to the possibilities offered by technology that is becoming increasingly widespread, the medicine could be tracked even at the moment it is thrown away. Based on existing experiences of smart baskets, which give information about their filling and optimize the collection processes, or that allow the collection of certain types of waste (for example, diapers and sanitary napkins, which if differentiated, can be recycled), during the Metadesign Course within the Product Design Bachelor's Degree at Politecnico di Milano, the students have developed a basket for the collection of drugs. With this example, we propose a design reflection on the traceability of the drug in its entire life cycle, acting both on the awareness and education of the user and on the management of the drug as waste.

7. Design culture within future care processes

There is one positive effect we can attribute to the pandemic state: that of having highlighted how little normality there is in the processes of care. Perhaps this is because the disease itself does not belong to the sphere of 'normality': all the complex practices that inhabit it and the behaviours it triggers are out of the ordinary, changing or distorting a person's everyday life. The accessibility of medicine, which is currently the main treatment practice, is a human right. To be considered as such, it is necessary to design new ways and new shapes of quality, safety, trust, friendliness for the patient, to make him/her feel in control and at ease when dealing with the healthcare system as a whole, compared to when he/she tries to manage his/her health status autonomously. Characteristics capable of promoting a new normality of care that is truly post-pandemic. In this sense, we have seen that the prerequisites are already in place in technology and policies to be able to intervene on certain customs and habits relating to the management of one's health, which were consolidated but which the pandemic crisis has eradicated.

The Design Culture can bring together the different knowledge and disciplines that affect the pharmaceutical sector and the processes of care. Indeed, as illustrated in the previous paragraphs, the design contribution can affect the different dimensions of care. It may involve the production, material and formal aspects of the medicine itself: thanks to the use of tools such as 3D printing, it is possible to create a truly personalized cure and design a custom treatment. It may concern the formal, graphic and material aspects of the packaging, and thus guide patients towards a better and more conscious interaction and experience of medicine use. It may address the management of home treatment and the relationships among the various actors of the process, investigating the communication potential through digital channels.

As a consequence of the pandemic situation, the often digital and virtual interactions among the patient, the medical staff and the pharmacist have become much more difficult; thus, all

the figures involved have had to adapt to communication tools and relationships not specifically designed for the management of care processes. The entire experience of care, from the purchase to the assumption of the medicine, has lost the degree of familiarity, control and security given by the direct and real interaction among the actors of the care process, amplifying the possibility of errors and related risks.

The potential offered by technology for the pharmaceutical sector, and the critical aspects that have emerged in the home care processes represent an opportunity: the Design Culture can indeed be an interpretative and project filter through which we can respond to the challenges of home care processes and interaction with drugs, keeping the human component at the centre.

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