Sustainable Drug Production and Consumption: Legal Profiles

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Abstract

The aim of the responsible production and consumption of drugs is to reduce the environmental and social impact and to promote human and environmental development in a sustainable manner. This requires the use of environmentally friendly resources, energy-efficient production processes, and the proper disposal of medicines. There is an urgent need for a cross-sectoral legal approach to the issue, which, while implying a new paradigm of contractual autonomy and a rethinking of the regulation of relations between private individuals, promotes the full protection of fundamental human rights in the long term, in solidarity, and from an intergenerational perspective.

Keywords

Production, Consumption, Sustainability, Drug, Waste, Pharmaceutical Packaging, Environmental Protection, Contractual Autonomy, Principle of Solidarity.

I. Introduction

The current general context of production and consumption, in which the effects of ongoing wars are compounded by those of the climate crisis, reveals the complexity and urgency of the challenge of sustainable development. There is growing awareness of the importance of responsible resource management as well as the inseparable link between human health and the environment. A strategic approach is called for, with the medium- and long-term goal of building production and consumption models resilient to future crises.[1] This is fully reflected in the pharmaceutical sector, where production and consumption are activities that have an increasing impact on the environment. The pharmaceutical industry is also one of the most energy-intensive in the world, its production processes require large amounts of natural resources, and produce a

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[1] Alleanza Italiana per lo Sviluppo Sostenibile (ASviS), *Produzione e consumo sostenibili* (2022), 7.

considerable amount of hazardous or toxic waste.[2] In this context, promoting the production and consumption of environmentally sustainable medicines is becoming increasingly important.

This requires on the one hand taking appropriate measures to reduce the pharmaceutical industry's impact on the environment and on the other hand improving the management of pharmaceutical waste. There is a critical need to strike the right balance between raising awareness and developing appropriate policies to prevent the potential negative environmental impacts of pharmaceuticals and to ensure access to safe and effective medicines for the benefit of public health.

This essay will press the need for action to be taken to reduce the environmentally harmful consequences of pharmaceutical waste and will raise the issue of the civil liability profiles of companies and consumers, all of whom are called upon to make their own active contribution to making the entire pharmaceutical production cycle sustainable.

Therefore, the fight against climate change and the concrete implementation of the ongoing ecological transition require not only a rethinking of the legal system, which must be based on a logic of sharing and care, in a perspective founded on solidarity, but also a renewed interpretation of legal relations between private individuals, which recognises the central role of the general community and the environment.[3]

Indeed, it is necessary to think of the legal system as a system that is not detached from social reality, but expressive of the contemporary culture that characterizes reality itself.[4]

It can be argued that, in the context of civil law, the contract can be conceptualized as a legal infrastructure with the potential to redesign the market, the production chain, and society in accordance with general principles and the particular principle of solidarity set

[2] C.E. Hoicka et al, 'Implementing a Just Renewable Energy Transition: Policy Advice for Transposing the New European Rules for Renewable Energy Communities' *Energy Policy*, 156, 6 (2021); J. Lowitzsch, 'The Consumer at the Heart of the Energy Markets?', in Id ed, *Energy Transition: Financing Consumer Co-Ownership in Renewables* (Cham: Springer International Publishing, 2019), 62; F. Azmat et al, 'Convergence of Business, Innovation, and Sustainability at the Tipping Point of the Sustainable Development Goals' *Journal of Business Research*, 167 (2023).

[3] F. Capra and U. Mattei, *L'ecologia del diritto. Verso un sistema giuridico in sintonia con la natura e la comunità* (Oakland: Berrett-Koehler Publishers, 2015), 27.

[4] On this subject, see L. Ammannati, 'Energia e ambiente: regolazione per la transizione', in M. Passalacqua ed, *Diritti e mercati nella transizione ecologica e digitale* (Padova: Cedam, 2021), 7; P. Perlingieri, 'Mercato, solidarietà e diritti umani' *Rassegna di diritto civile*, 88 (1995), now in Id, *Il diritto dei contratti fra persona e mercato. Problemi del diritto civile* (Napoli: Edizioni Scientifiche Italiane, 2003), 251.

out in Art 3 of the Constitution of the Republic of Italy. Such an outcome could be achieved in pursuit of sustainable development objectives.[5]

In the EU's recent interventions[6] focused on the green transition,[7] increasing importance is given to the legislative factor and, more generally, to the legal component in guiding and supporting the transition towards sustainability.

In Italy, unlike in other Member States, the existence of a rigid Constitution requires a balancing act between the emerging needs of the market and the production chain – including the pharmaceutical industry – and the protection of the individual, favouring legislative and hermeneutic solutions that avoid, even in an intergenerational perspective, injuries to health, the environment, and the human person.[8]

An analysis of the impact of European legislation on the production and consumption of pharmaceuticals allows us to identify potential avenues for the reformulation of legal institutions. This analysis also enables an evaluation to be made of how well the objective of sustainable development, which guides European legislators, aligns with the comprehensive protection of fundamental human rights.[9]

It is evident that novel profiles will emerge, encompassing new strategies and behavioural constraints imposed on companies engaged in the production process and consumers in their practices. These developments will have ramifications for the rights and obligations of individuals and companies operating within the same sector. This will facilitate the promotion of a circular, just, and

[5] L. Ruggeri, 'Diritto della transizione e sostenibilità: tra tutela del mercato e protezione della persona', in L. Ruggeri and A.E. Caterini eds, *Produzione e consumo sostenibili tra politiche legislative e prassi applicative* (Napoli: Edizioni Scientifiche Italiane, 2023), 32; J. Van Zeben, 'The Role of the EU Charter on Fundamental Rights in Climate Litigation' 2 *Wageningen Law Series* (2021).

[6] Here, reference is made to the 'European Green Deal measure', the 'Fit for 55 Package', and European Parliament and Council Directive 2024/1760/EU of 13 June 2024 on corporate sustainability due diligence and amending Directive (EU) 2019/1937 and Regulation (EU) 2023/2859 [2024] OJ L series.

[7] For a closer look at the EU multilevel regulatory framework, see A. Jordan et al, 'EU Environmental Policy at 50: Retrospect and Prospect', in A. Jordan and V. Gravey eds, *Environmental Policy in the EU* (London-New York: Routledge, 2021), 357; S. Pätäri et al, 'Global Sustainability Megaforces in Shaping the Future of the European Pulp and Paper Industry Towards a Bioeconomy' 66 *Forest Policy and Economics*, 47 (2016).

[8] P. Perlingieri, 'La grande dicotomia diritto positivo-diritto naturale', in Id, *Interpretazione e legalità costituzionale. Antologia per una didattica progredita* (Napoli: Edizioni Scientifiche Italiane, 2012), 20.

[9] L. Ruggeri, 'Diritto della transizione e sostenibilità', n 5 above, 33.

sustainable economic model that respects the fundamental rights of the individual, in accordance with the intentions of the European legislator.

II. Production Processes and Drug Consumption Practices. Corporate Liability and Consumer Protection Profiles

The business community, including major pharmaceutical corporations, is obliged to assume a pivotal role in bolstering the legal culture of environmental sustainability. This entails the formulation of novel production and consumption practices aligned with the interests of the broader public and the pursuit of collective well-being.[10]

As will be seen below, in the European regulatory landscape, the final adoption of the Directive on Corporate Due Diligence for Sustainability[11] concluded the process through which Europe aims to make it mandatory for companies to commit to environmental sustainability. The aim of the Directive is to promote responsible business conduct through the systematic integration of sustainability principles into the values on which business decisions are based, thus promoting fair competition in the market. This new regime aims to give legal certainty to corporate responsibility by clarifying the legal consequences arising from it.

Shifting the focus more specifically to the pharmaceutical sector, Europe's medicines legislation[12] is the main tool for ensuring the

[10] M.E. Porter and M.R. Kramer, 'Creare valore condiviso: come reinventare il capitalismo e scatenare un'ondata di innovazione e crescita' 1 *Harvard Business Review*, 62-77 (2011).

[11] Reference is made to the recent European Parliament and Council Directive 2024/1760/EU.

[12] Among the various EU regulatory interventions, European Parliament and Council Directives 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L311/67, 2008/98/EU of 19 November 2008 on waste and repealing certain Directives [2008] OJ L312/3 and 2011/65/EU of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment [2011] OJ L174/88 establish rules on the restriction of the use of certain dangerous substances in electrical and electronic equipment used in the healthcare sector. Equally important is European Parliament and Council Regulation 2006/1907/EC of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC [2006] OJ L396/1, which requires pharmaceutical companies to evaluate the chemical substances they produce or import, ensuring their safe handling. See A. Spina, 'The Regulation of

quality, safety, and efficacy of medicines, as well as their environmental safety. A pharmaceutical environmental risk assessment is mandatory for all marketing authorization applications for medicinal products and is considered when assessing the benefit/risk ratio of medicinal products.

On this topic, within the European regulatory framework, the Strategic Approach to Pharmaceuticals in the Environment, adopted by the EU Commission with the aim of highlighting the critical issues related to the problem of environmental pollution from medicines,[13] deserves consideration. This initiative, taking place against a backdrop of growing concern about the impact of pharmaceuticals on the environment and health, has made crucial progress towards the creation of a solid regulatory framework aimed at ensuring sustainable drug production cycles in the European Union.

But there is more. Recently, with Regulation 2024/795/EU,[14] Europe has introduced a new Strategic Technology Platform (STEP) to strengthen European competitiveness and resilience in strategic sectors by reducing dependence on foreign supply chains. The objective is to reinforce production sectors, with particular focus on medical and pharmaceutical technologies. With this Regulation, Europe aims to introduce highly efficient and environmentally friendly platforms and techniques for the identification and production of active pharmaceutical ingredients.

The recent developments in European regulatory policy show that the pursuit of sustainable practices in pharmaceutical manufacturing is inextricably linked to the implementation of a new and challenging strategic approach for companies. This necessitates a comprehensive reassessment of objectives and the incorporation of environmental and social considerations throughout the production process, with the objective of transforming potential

Pharmaceuticals Beyond the State: EU and Global Administrative Systems' *Global Administrative Law and EU Administrative Law*, 257 (2011).

[13] Reference is made to the Communication of Commission EU to the European Parliament, the Council and the European Economic and Social Committee 'An EU Policy Approach to the Environmental Impact of Medicines' COM(2019) 128 final.

[14] European Parliament and Council Regulation 2024/795/EU of 29 February 2024 establishing the Strategic Technologies for Europe Platform (STEP) and amending Directive 2003/87/EC and Regulations (EU) 2021/1058, (EU) 2021/1056, (EU) 2021/1057, (EU) No 1303/2013, (EU) No 223/2014, (EU) 2021/1060, (EU) 2021/523, (EU) 2021/695, (EU) 2021/697 and (EU) 2021/241 [2024] OJ L series.

risks into opportunities through the renewal of business operations.[15]

However, the concept of sustainability is often perceived by some companies as a cost, especially in the short term.[16] This is illustrated by the aforementioned European Directive 2024/1760 which requires large pharmaceutical companies to meticulously manage social and environmental impacts throughout the production and distribution cycle of medicines. This implies that they are answerable for the consequences of failing to fulfil their due diligence obligations, which may result in human rights violations or environmental damage.[17] In acting in compliance with their due diligence obligations, businesses can demonstrate their commitment to ethical and sustainable business practices in compliance with the Directive. Doing so can enhance their reputation and increase trust in the market.

In the absence of compliance with the Directive's due diligence obligations, the key legal issue arises of what consequences, if any, are imposed on companies in such instances.

Where a breach of obligations to ensure respect for human rights as well as environmental protection throughout the production chain is identified, companies will have to take appropriate measures to mitigate, halt, or minimize the negative impacts resulting from their activities, the activities of their subsidiaries, and the activities of their business partners along their business chain. Companies will be held liable for unfair damages in the event of a violation, whether intentional or negligent, of the due diligence obligations provided for by the Directive if concrete damage to a natural or legal person derives from such unlawful conduct. On this point, in Italy, given the broad protection enjoyed by the legal asset

[15] On the evolution of corporate law, see G. Schneider, 'L'emergenza della sostenibilità nel prisma del new normal del diritto d'impresa europea' *Nuovo diritto societario*, 850 (2022).

[16] F. Denozza, 'Lo scopo della società, tra short-termism e stakeholders empowerment' 1 *Orizzonti del diritto commerciale*, 32 (2021); M. Libertini, 'Impresa e finalità sociali. Riflessioni sulla teoria della responsabilità sociale dell'impresa' *Rivista delle società*, 25 (2009).

[17] On the topic of the evolution of European company law, see G. Schneider, n 15 above. In this regard see P. Perlingieri, 'Persona, ambiente e sviluppo', in M. Pennasilico ed, *Contratto e ambiente. L'analisi «ecologica» del diritto contrattuale* (Napoli: Edizioni Scientifiche Italiane, 2016), 325.

'environment', both in doctrine[18] and in jurisprudence,[19] the functional profile of environmental protection is now configured in a dual perspective; in other words, environmental protection is conceived not only as a compensatory function, but also as a restorative and reintegrative function. This theorization of environmental protection does not reduce protection to a mere monetary equivalent of the injuries caused, but requires the prevention of the occurrence of damage and, if damage has occurred, places the burden of removing the event as well as the resulting burdens on the responsible party.[20]

As for the role of consumers, in respect of the sustainable development objectives imposed by Europe, it emerges that they are increasingly interested in knowing what attention the producers of the goods they purchase pay to issues such as environmental and health protection, along the entire production chain. Pharmaceutical companies are no exception precisely because of the sensitive nature of the sector in which they operate, which concerns a commodity as precious as human health. While it is true that the role of pharmaceutical entrepreneurship is widespread in the promotion of sustainability-oriented production models, it cannot be ruled out that consumers are also called upon to contribute in this direction by adopting conscious and responsible consumption practices, which the companies themselves must encourage and not hinder. After all, 'responsible consumption is an action by which the informed and aware consumer assesses the social value expressed in goods and the environmental impact of the company that produces them'.[21] This assessment serves to protect the interests of both the consumer and the wider community in the medium and long term. Consequently, there is a transition from a passive to an active role, whereby individuals are empowered to influence market dynamics through their purchasing decisions and to intervene in corporate

[18] On the impact of the principle of solidarity on the category of climate change damage, see M. Zarro, *Danno da cambiamento climatico e funzione sociale della responsabilità civile* (Napoli: Edizioni Scientifiche Italiane, 2022), 153.

[19] For further information, see the judgment of Consiglio di Stato 22 October 2019 no 10.

[20] L. Ruggeri, 'Which Law for Transition? The Market and the Person in a Prism of Sustainability', in L. Ruggeri and K. Zabrodina eds, *Making Production and Consumption Sustainable: A Global Challenge for Legislative Policies, Case Law and Contractual Practices. Guidelines for Changing Markets* (Wien: SGEM World Science, 2023), 38; V. Cariello, 'Per un diritto costituzionale della sostenibilità (oltre la «sostenibilità ambientale»)' *Orizzonti del diritto commerciale*, 427 (2022).

[21] For the notion of 'sustainable consumption', see ASviS, n 1 above, 31.

strategies to ensure genuine focus on the social dimension, while respecting environmental resources for all.[22]

It is imperative that consumers and patients are made aware of the potential risks associated with the consumption of medicines. This is to ensure that their use is neither excessive nor inappropriate. The reduction of the negative impacts of pharmaceuticals and the assurance that they continue to enhance the quality of life without compromising the health of the environment and future generations can be achieved only through collective action and a general duty of solidarity.

Europe's intention to empower the consumer in the green transition is clear.[23] Prominent in this respect is European Parliament and Council Directive 2024/825/EU[24] which, by banning misleading communications and promoting transparency and environmental responsibility in commercial practices, aims to promote greater consumer protection in every sector. This reform document provides for new rules to ensure that all EU consumers, wherever they live or shop in the EU, can enjoy a common, high level of protection against risks and threats to their safety and economic interests, as well as to enhance the ability of consumers to protect their own interests. Furthermore, these rules aim to strike a balance between the need to control information and communications that may influence consumers' purchasing choices by virtue of their moral sensitivities, their attitude to sustainability, and the risk of consumer confusion. This overcomes the limits that the qualitative information asymmetry inherent in sustainability claims may present with respect to ethically intended consumption, since these are also subject to the control and protection tools provided by the new regulatory dictate of the Due Diligence Directive. The purpose of this regulatory update would be to enable consumers to make more conscious and environmentally friendly purchasing choices, as well as to strengthen their protection against unreliable or false environmental sustainability claims by prohibiting the

[22] P. Perlingieri, 'Mercato', n 4 above, 257.

[23] M. Giobbi, *Il consumatore energetico nel prisma del quadro regolatore italiano ed eurounitario* (Napoli: Edizioni Scientifiche Italiane, 2021), 5; P.M. Sanfilippo, 'Tutela dell'ambiente e "assetti adeguati" dell'impresa: compliance, autonomia ed Enforcement' 6 *Rivista di diritto civile*, 1010 (2022).

[24] Reference is made to European Parliament and Council Directive 2024/825/EU amending Directives 2005/29/EC and 2011/83/EU as regards empowering consumers for the green transition through better protection against unfair practices and through better information [2024] OJ L series.

dissemination of misleading information.[25] In sum, legal certainty for professionals is enhanced, while consumer confidence in environmentally friendly products and accurate information regarding their environmental impact is also strengthened.

A recent ruling of the Court of Justice is also of interest in this regard,[26] due to the multiplier effect resulting from the application of the rules on judicial cooperation between Member States in matters of intentional or negligent torts, regardless of the place where the harmful event occurred or may occur. This is with a view to counteracting the possible violation of rules set up to protect the environment. In particular, this ruling is relevant insofar as it provides that producers of goods and services operating in Europe, including economic operators in the pharmaceutical sector, must ensure compliance with the rules established by European law and which may be assessed not only before the national jurisdiction in which they operate, but also before the courts of the other Member States of the Union. This is done in order to counteract the possible violation of rules set out to protect the environment.

The judgment explicitly refers to the recently introduced European Parliament and Council Directive 2024/825/EU,[27] thereby empowering consumers to play a greater role in the green transition. This is achieved by enhancing protection from unfair practices and information asymmetries.[28] In all sectors, including the pharmaceutical industry, where consumers perceive non-compliance with the behavioural constraints imposed on companies throughout the production chain, legal action may be taken to enforce compliance. This may be done by activating the legal instrument provided for in the event of a violation of the rules protecting the environment, namely the action for damages for civil liability.

[25] G. Ballerini, 'Spunti problematici su sostenibilità, modifiche alla italiana e Proposta di Direttiva Costituzione europea sulla dovuta diligenza' *Studium iuris*, 1001 (2022); E. Barcellona, 'La Sustainable Corporate Governance nelle proposte di riforma del diritto europeo: a proposito dei limiti strutturali del cd stakeholderism' *Rivista delle società*, 5 (2022).

[26] Case C-81/23 *MA* v *F SpA, FI SpA*, Judgment of 22 February 2024, available at https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:C_202402398.

[27] European Parliament and Council Directive 2024/825/EU.

[28] See note to judgment: L. Idot, 'Règlement "Bruxelles I Bis" – Règle de compétence en matière délictuelle' *Europe*, 3 (2024).

III. Environmental Sustainability and the New Paradigm of Contractual Autonomy in the Drug Production Chain

The introduction of a revised framework of behavioural constraints concerning the forecasting and assessment of the potential risks that a given business activity may pose to human rights or the environment, and of new consumer protection profiles, places the individual and the realization of shared well-being at the centre, with a consequent change in the contractual paradigm.[29] In this regard, in Italy, with a view to sustainability, it is the constitutional principles that have made an important contribution to the protection of the environment, health, and the human person.[30]

The potential role can be considered of merit-based evaluation, conducted in accordance with constitutional values, in relation to supply contracts that are integral to the drug production and distribution chain. However, these contracts could potentially lead to human rights violations,[31] particularly in instances where they result in environmental damage due to the improper disposal of toxic substances.

If the environment in the Italian constitutional context is conceptualized as a common good that must be protected to facilitate the full and free development of the human person, it follows that the interpreter, who is tasked with carrying out checks of legitimacy and merit in accordance with the pivotal values of the system, must verify the conformity of the contractual arrangement to the value-environment. This process of verification thus allows for the attribution of an authentic 'ecological' connotation to acts of private initiative.[32] From this perspective, the act of contractual autonomy, in contrast with the general interest in the protection of the environment (as well as with other interests, such as the protection of health, psychophysical integrity, and, in the broader

[29] As to the preceptive scope of the principles, see S. Zuccarino, 'Sostenibilità ambientale e riconcettualizzazione del contratto' *Annali della Società Italiana degli Studiosi di Diritto Civile*, 77 (2022).

[30] In this topic, see V. Cariello, 'Per un diritto costituzionale', n 20 above, 437.

[31] S. Polidori, 'Il controllo di meritevolezza sugli atti di autonomia negoziale', in G. Perlingieri and M. D'ambrosio eds, *Fonti, metodo e interpretazione. Primo incontro di studio dell'associazione dei dottorati di diritto privato* (Napoli: Edizioni Scientifiche Italiane, 2017), 407; see also E. Caterini, *Sostenibilità e ordinamento civile. Per una riproposizione della questione sociale* (Napoli: Edizioni Scientifiche Italiane, 2018), 22.

[32] A. Jannarelli, 'Principi ambientali e conformazione dell'autonomia negoziale: considerazioni generali', in M. Pennasilico ed, *Contratto e ambiente. L'analisi "ecologica" del diritto contrattuale* (Napoli: Edizioni Scientifiche Italiane, 2016), 21.

sense, human dignity), cannot be considered to merit protection.[33] The absence of the contractual criterion of merits, whether at the level of the contract as a whole or of individual clauses, gives rise to a pathological phase of the contract, which in turn entails the consequent invalidity of the contract in its entirety or of individual clauses. The issue of control, specifically regarding the evaluation of merits, must be conducted in a concrete manner and about all acts of negotiation, whether typical or atypical. This extends even to those adopted within the context of the pharmaceutical production chain. The objective is to prevent the potential consequence that a private initiative, though causally lawful, may be deemed undeserving of protection if it fails to align with the concrete environmental interest.[34]

In light of the aforementioned considerations, it becomes evident that the evolving concept of contractual autonomy establishes protection of the environment as an intrinsic constraint within the scope of economic operator activities.[35]

This suggests that the conclusion of contracts pertaining to production processes, such as supply contracts within the pharmaceutical sector, means that each economic operator must commit to manufacturing products in accordance with production standards that are aligned with sustainability criteria, which should be explicitly stated[36] in dedicated clauses.[37]

Indeed, within the context of Italian private law, the notion of sustainability, as it pertains to sustainable development, is conceptualized as a production cycle that is integrated with social and environmental requirements, with due consideration of the needs of future generations in an intergenerational framework. The same doctrine[38] has repeatedly pointed out how, under Art 3 *quater*

[33] In this sense, see also M. Pennasilico, 'Contratto ecologico e conformazione dell'autonomia negoziale' 1 *Rivista quadrimestrale di diritto dell'ambiente*, 820 (2017) who writes: 'the principle of sustainable development thus constitutes a parameter of merit for ecological contracts'.

[34] S. Persia, 'Proprietà e contratto nel paradigma del diritto civile sostenibile' 1 *Rivista quadrimestrale di diritto dell'ambiente*, 17 (2018).

[35] M. Pennasilico, 'Sviluppo sostenibile, legalità costituzionale e analisi "ecologica" del contratto' *personaemercato.it*, 38 (2015); G. Perlingieri, 'Sostenibilità, ordinamento giuridico e «retorica dei diritti». A margine di un recente libro' *Il foro napoletano*, 101 (2020).

[36] European Parliament and Council Directive 2024/825/EU is recalled.

[37] S. Landini, 'Clausole di sostenibilità nei contratti tra privati. Problemi e riflessioni' *Diritto pubblico*, 611 (2015); R. Rolli, 'Contract Governance e sostenibilità' *Dirittobancario.it*, 2 (2024).

[38] In regard, see S. Landini, 'Clausole di sostenibilità', n 37 above, 627.

of the Environment Code,[39] every human activity must conform to the principle of sustainable development 'so that the principle of solidarity is also included in the dynamics of production and consumption in order to safeguard and improve the quality of the environment also for the future'. Furthermore, the Environmental Code stipulates responsibility to safeguard the environment for private entities, thereby substantiating the 'ecological' implications of contractual autonomy.

Subsequently, it is observed that the functional profile of the contract is in alignment with the constitutional objective of ensuring the 'full development of the human person' within a framework of solidarity and intergenerational responsibility (Art 3, para 2 of the Constitution).[40]

The necessity to safeguard the individual and future generations has established a novel contractual paradigm, defined as a contract for the protection of unspecified third parties or the entire community;[41] indeed, considering the principle of constitutional solidarity and the prospective relationship between contract and environment, the boundaries of contract relativity are transcended, and the protection of the community is justified. This is because the contract now has a direct impact on the community, rather than merely reflecting it.[42]

In light of this reappraisal of the concept of the contract, the activities inherent in the production chain of pharmaceutical companies are unified by a novel contractual paradigm. This paradigm is defined by its capacity to suggest novel expansions regarding its functional profile and the evaluation of the merits of private autonomy, considering the social and environmental purposes now enshrined in Art 41 of the Constitution. Consequently, it can be seen to perform a conforming function within the context of the so-called ecological contract.[43] In this sense, the function of

[39] Refer to decreto legislativo 3 April 2006 no 152.

[40] M. Pennasilico, 'La nozione giuridica di ambiente nella prospettiva sistematica e assiologica', in Id, *Manuale di diritto civile dell'ambiente* (Napoli: Edizioni Scientifiche Italiane, 2016), 19.

[41] G. Corso, 'Categorie giuridiche e diritto delle generazioni future', in F. Astone et al, *Cittadinanza e diritti delle generazioni future. Atti del Convegno di Copanello, 3-4 luglio 2009* (Soveria Mannelli: Rubbettino, 2010), 9.

[42] U. Mattei and A. Quarta, 'Tre tipi di solidarietà. Oltre la crisi nel diritto dei contratti' *giustiziacivile.com* (2020); M. Pennasilico, 'La "sostenibilità ambientale" nella dimensione civil-costituzionale: verso un diritto dello sviluppo umano ed ecologico' 3 *Rivista quadrimestrale di diritto dell'ambiente*, 4 (2020).

[43] G. Carapezza Figlia, 'I rapporti di utenza dei servizi pubblici tra autonomia negoziale e sussidiarietà orizzontale' *Rassegna di diritto civile*, 462 (2017).

the contract extends beyond the contracting parties, with the potential to impact the positions of third parties. This places the contract in an ultra-individual vision of its effectiveness. In this framework, private self-regulation performs the function of regulation and the implementation of general interests,[44] so that the acts of autonomy of private individuals or associations, which realize general interests of an environmental nature, whose relevant profile is the protection of a common good with shared and multiple enjoyment, will also produce effects towards third parties, thus acquiring external effectiveness.[45] Third parties, which are external to the contract but share the same common interests and are represented in the contractual regulation, will claim to be recipients of benefits derived from the stipulation and, more generally, of rules of conduct. From this perspective, the contract, which is intended to regulate multiple ecologically oriented interests, fulfils its effects in a dynamic and intergenerational dimension.[46] This involves those who, at a different stage and after its conclusion, encounter the environmental legal asset.[47]

This shift towards the sustainability of exchange is now an indication that our traditional classificatory schemes have been rendered obsolete. The theory and the very notion of contract can no longer be constructed in isolation of the specific case in question, considering the impact of each individual contract on the environment and the individual.[48]

From this perspective, contractual practice and recent European legislation[49] propose the inclusion of contractual sustainability clauses, which demonstrate how the contract can serve as a tool for enforcing and governing sustainability in the context of the current situation. [50]

[44] S. Persia, 'Proprietà', n 34 above, 18.

[45] A. Nervi, 'Beni comuni, ambiente e funzione del contratto', in M. Pennasilico ed, *Contratto e ambiente. L'analisi "ecologica" del diritto contrattuale* (Napoli: Edizioni Scientifiche Italiane, 2016), 48.

[46] On the intergenerationality of civil law institutions qualified as 'sustainable', see E. Caterini, 'Sostenibilità', n 31 above, 88.

[47] M.G. Cappiello, 'Il contratto "a rilevanza ecologica": nuovi scenari civilistici a tutela dell'ambiente' *Rivista quadrimestrale di diritto dell'ambient*, 127 (2020).

[48] M. Pennasilico, 'Contratto ecologico', n 33 above, 822.

[49] This section refers to several key international and European legislative initiatives, including the UN 2030 Agenda, the 'European Green Deal', the 'Fit for 55 Package', European Parliament and Council Directives 2022/2464/EU of 14 December 2022 amending Regulation (EU) No 537/2014, Directive 2004/109/EC, Directive 2006/43/EC and Directive 2013/34/EU, as regards corporate sustainability reporting [2022] OJ L322/15, and 2024/1760/EU on companies' duty of care for sustainability.

[50] R. Rolli, 'Contract Governance', n 37 above, 5.

In Italy, emblematic in this regard, also with reference to drug production processes, has been the orientation of the Italian Supreme Court[51] concerning immissions.

Italian Supreme Court judges have specified that the provision contained in Art 844 of the Italian Civil Code, 'in providing for the judge's assessment of the balancing of the needs of production with the reasons of property, must be interpreted, taking into account that the limit of the protection of health and the environment is to be considered intrinsic to the activity of production as well as to neighbourhood relations, in the light of a constitutionally oriented interpretation of the goods protected by Art 844 of the Italian Civil Code'. Such an interpretation positions the right to a normal quality of life more highly than the needs of production. It is evident, therefore, that even in the pharmaceutical sector, environmental sustainability and related contractual clauses integrate stringent obligations where prescribed by law or contract and operate as a general clause intrinsic to the system.

The proposed model is entirely consistent with the principles of the circular economy[52] as originally conceived by the European Union. This concept proposes a type of sustainable production that favours recyclability, with the objective of reducing the environmental impact throughout the production chain and transforming waste from one sector into raw material for another. In this regard, it is imperative to direct attention towards the management of pharmaceutical waste, particularly in relation to packaging waste, a subject that has recently been significantly impacted by legislative intervention.

IV. Sustainable Pharmaceutical Waste Management. Pharmaceutical Packaging Meets Environmental Sustainability

As highlighted by the European Commission,[53] the effective and sustainable management of pharmaceutical waste can serve to reduce the environmental impact and contribute to the protection of ecosystems.

[51] Refer to the Judgment of Corte di Cassazione 8 March 2010 no 5564, *Giustizia civile*, 820 (2010).

[52] J. Kirchher et al, 'Conceptualizing the Circular Economy: An Analysis of 114 Definitions' 127 *Resources, Conservation and Recycling*, 221 (2017).

[53] See the above-mentioned Communication of the Commission to the European Parliament, the Council and the European Economic and Social Committee 'An EU Policy Approach to the Environmental Impact of Medicines' COM(2019) 128 final.

A few environmental sustainability practices have been introduced at the European level with the objective of providing guidance on the management of pharmaceutical waste. These include not only the strategy of promoting the prescription of adequate quantities of medicines to avoid surpluses by supporting patient awareness and education campaigns, but also the sustainable practices of collecting and disposing of unused medicines, as well as recycling medicine packaging and reusing, where possible, unopened and unexpired medicines.

As known, the most recent legislative solutions introduced by Europe have the objective of incorporating sustainable waste management into the green transition. This is to be achieved through the implementation of more rigorous policies and the adoption of innovative technologies, with the aim of reducing the environmental impact of pharmaceutical waste and protecting public health. The management of pharmaceutical waste is inextricably linked to the role of pharmaceutical packaging.

It is anticipated that the implementation of a circular economy for packaging will facilitate the decoupling of economic growth from the use of natural resources, thereby contributing to the achievement of climate neutrality by 2050 and the halting of the loss of biodiversity. This suggests that the management of pharmaceutical packaging waste can be effectively aligned with environmental sustainability.

In the context of pharmaceutical packaging, the issue of recycling has assumed significant importance, to the extent that it cannot be regarded as a mere peripheral concern by the pharmaceutical industry. Indeed, pharmaceutical companies are increasingly being called upon to consider the recyclability of their products at the end of their use cycle, with a view to favouring, wherever possible, packaging with a lower environmental impact. Upon the introduction of a new pharmaceutical product to the market, it is subjected to a comprehensive evaluation process, which encompasses the assessment of its packaging. In the event of a change to the packaging, the drug in question must undergo the entire evaluation procedure once more. This is a lengthy and costly process, which contributes to pharmaceutical companies being constrained by their existing packaging choices. This, in turn, leads them to make compromises on sustainability that are, at best, only partially effective.

In the context of packaging waste, the recent Proposal for a Regulation approved by the EU Parliament[54] is a pertinent point of reference. This legislative proposal, which is supported by the case law of the Court, introduces certain exemptions for primary packaging that is in direct contact with medicines and for outer packaging. However, it also has the potential to exert a restrictive influence on the pharmaceutical sector.[55]

Indeed, particular categories of packaging are exempt from the regulations pertaining to recyclability in order to guarantee the safety and protection of human health. The exemptions pertain to primary packaging that is in direct contact with medicines, and outer packaging that is essential for maintaining the quality of the product. The objective of this regulatory provision is to guarantee that the specific requirements for the protection of medicines are not undermined.

One of the most intriguing aspects of the proposed regulation is the establishment of a unified packaging system based on harmonised standards across Member States. This is intended to address the limitations imposed by the current lack of harmonization in the regulatory framework on this subject. Additionally, the transition towards a harmonized and homogeneous regulation of a sustainable packaging system has been significantly influenced by the case law of the European Court of Justice.[56]

Indeed, in a recent case, the Court observed that the standards set by the regulation are designed to achieve a delicate equilibrium between the objective of free movement of packaging products and the protection of general interests, including the environment. The Court ruled that, in the absence of authorization by the European framework for Member States to adopt more restrictive standards with regard to certain sectors (such as pharmaceuticals), and in the absence of scientific evidence to show that the requirements defined at the European level are insufficient, the balance cannot be called into question by national authorities without precise limits and

[54] European Commission, 'Proposal for a Regulation of the European Parliament and of the Council on packaging and packaging waste, amending Regulation (EU) 2019/1020 and Directive (EU) 2019/904 and repealing Directive 94/62/EC' COM(2022) 677 final. This Proposal for an EU Regulation was approved by the EU Parliament on 15 March 2024.

[55] C. Zervos, 'Imballaggi green, nuove norme UE su riduzione rifiuti. Esenzioni sui farmaci: ecco quali sono' *Farmacista33.it*, 2 (2024).

[56] In this context, reference is made to the recent Case C-86/22 *Papier Mettler Italia S.r.l.* v *Ministero della Transizione Ecologica and Ministero dello Sviluppo Economico*, Judgment of 21 December 2023.

requirements.[57] It thus becomes evident that the recently proposed European measures, despite their focus on the entire packaging chain, also serve to reflexively promote a significantly heightened level of environmental and human health protection.

V. Concluding Remarks

Considering the current European regulatory framework, there is a compelling need to advance sustainable development, which entails the ongoing enhancement of society to guarantee collective well-being within a framework of solidarity. This implies that in the pharmaceutical sector, there is a need to achieve a balance between the use of resources and the protection of the environment, as well as to promote responsible patterns of production and consumption. Previously, environmental concerns were regarded as an external factor of European policies, with a primary focus on economic aspects. However, recent developments have led to a change in perspective, with environmental considerations now seen as an intrinsic element of the development process, in line with the concept of 'sustainable development'.[58] The proposition put forth is that there must be a balance between antithesis and symbiosis with respect to the environment and human development.[59]

In order to prevent not only the market but also democracy from becoming regimes that exploit natural resources without considering the future, it is necessary to base the new rules on intergenerational responsibility and promote a new ecological culture to induce appropriate and sustainable behaviour in the long term. The Italian Constitutional Court expressly referred to the concept of environmental sustainability from an intergenerational perspective in its ruling no 105 of 2024: 'the perspective of protection indicated by the constitutional legislator is of particular interest, which not only refers to the interests of individuals and the

[57] In this regard, see L. Butti, 'Imballaggi e rifiuti di imballaggio. Divieto della commercializzazione di sacchetti di plastica non biodegradabili per l'asporto delle merci' *Rivista giuridica dell'ambiente online*, 5 (2024); T. Reeves, 'L'imballaggio in Europa, Italia: il mercato e i fornitori negli anni '90' *Economist Intelligence Unit*, 3 (1990); G. Quadri, 'La gestione dei rifiuti tra contrastanti interessi costituzionalmente tutelati', in F. Lucarelli ed, *Ambiente, territorio e beni culturali nella giurisprudenza costituzionale* (Napoli: Editoriale Scientifica, 2006), 3.

[58] K. Parella, 'Protecting Third Parties in Contracts' 58 *American Business Law Journal*, 335 (2021); M.A. Ciocia, 'Le tappe dello sviluppo sostenibile', in Id and C. Ghionni eds, *Attività d'impresa e sviluppo sostenibile* (Napoli: Edizioni Scientifiche Italiane, 2021).

[59] M. Pennasilico, 'Sviluppo sostenibile', n 35 above, 40.

community in the present moment, but also extends to the interests of future generations, towards which the present generations have a precise duty to preserve the conditions so that they too can enjoy an environmental heritage that is as intact as possible'.[60]

Italian constitutional jurisprudence is thus aligned with that of France: the decision of the Conseil constitutionnel of 27 October 2023 in fact affirmed that the legislator, when adopting measures likely to have a serious and lasting impact on the environment, must verify that choices intended to meet the needs of the present do not in fact compromise the ability of future generations to decide on the matter, preserving their freedom of choice.[61]

In such a scenario, it is necessary to rethink and revisit, even in the pharmaceutical production chain, the traditional legal schemes of the contract and opt for the implementation of new models that consider the contract as an ecological system, which, oriented to the principle of solidarity, involves the interests of the parties and the general community by going beyond the relativity of effects. Third parties and the community must be involved in the negotiation phase of the contract through consultation and information procedures and must have the right to appeal in the event of violation of the right to be consulted and the right to receive clear and correct information.

The transition from an instrument regulating the individual and selfish interests of the parties to an instrument regulating collective interests makes it possible to state that the contract increasingly escapes the distinction between the public and the private. Even if concluded between private parties, the contractual regulation is necessarily shaped by the environmental interest, thus going beyond the reasons of the individual.[62] The ecological contract,[63] in conclusion, is a sustainable contract with external effectiveness aimed at realizing the fundamental rights of the human person and contributes, in this sense, to the implementation of social justice in an intergenerational perspective.

[60] On this point, in doctrine, see P. Pantalone, *La crisi pandemica dal punto di vista dei doveri. Diagnosi, prognosi e terapia dei problemi intergenerazionali secondo il diritto amministrativo* (Napoli: Editoriale Scientifica, 2023); G. Tulumello, 'Lo sviluppo sostenibile e la lotta al cambiamento climatico fra disciplina costituzionale e diritto dell'U.E.: la centralità della categoria dell'effettività e il ruolo della tutela giurisdizionale' *Giustizia amministrativa*, 5 (2024).

[61] Conseil constitutionnel 27 October 2023 no 2023-1066 QPC.

[62] S. Persia, 'Proprietà', n 34 above, 20.

[63] M. Pennasilico, 'Contratto ecologico', n 33 above, 823.

What is expected as a result is a 'transversal' law,[64] understood as a law on human and ecological development, in other words an innovative discipline based on the recovery of the age-old harmony between man and nature and the subordination of the ruinous primacy of the economy to the full protection of ecosystems and biodiversity. This will strengthen resilience, facilitate the transition from environmental sustainability as a problem to environmental sustainability as a solution,[65] and restore balance and total synergy between economic growth and ecological development, in every sector, including the pharmaceutical one.

Pharmaceutical companies are the primary actors in this process, along with consumers. They are responsible for implementing new and responsible production processes and adopting conscious consumption practices. These actions ensure the conservation or use of natural resources in line with the needs of the community and the full protection of a series of interests.[66] These interests can be traced back to the primary value of the human person. It is imperative to acknowledge that the complete and uninhibited development of the human person is contingent upon the prudent stewardship of the environment.[67] This must be done with a keen understanding of the historical yet intrinsic symbiotic relationship between humanity and the natural world.

[64] For further information on this topic, see P. Dell'Anno, 'Il ruolo dei principi del diritto ambientale europeo: norme di azione o di relazione?', in D. Amirante ed, *La forza normativa dei principi. Il contributo del diritto ambientale alla teoria generale* (Padova: CEDAM, 2006), 134.

[65] M. Pennasilico, 'La "sostenibilità ambientale" nella dimensione civil-costituzionale: verso un diritto dello "sviluppo umano ed ecologico"' 3 *Rivista quadrimestrale di diritto dell'ambiente*, 8 (2020).

[66] A. Nervi, 'Beni comuni', n 45 above, 51; M. Pennasilico, 'Sviluppo sostenibile', n 35 above, 44.

[67] P. Perlingieri, 'Persona, ambiente e sviluppo', n 17 above, 339.