

# The Italian Law Journal



## Special Issue

### *Sustainable Legal Infrastructures: Comparative Responses Across Cultures and Systems*



edited by Lucia Ruggeri, Lécia Vicente and Sara Zuccarino



Edizioni Scientifiche Italiane

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**THE ITALIAN LAW JOURNAL**

*An International Forum for the Critique of Italian Law*

Special Issue

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**Table of Contents**  
The Italian Law Journal  
Special Issue

***Sustainable Legal Infrastructures: Comparative Responses Across Cultures and Systems***

edited by Lucia Ruggeri, Lécia Vicente and Sara Zuccarino

LÉCIA VICENTE, <i>Expanding the Legal Dimensions of Sustainability</i> .....	1
LUCIA RUGGERI, <i>Corporate Due Diligence Between the Needs for Implementation of Sustainability and Protection of Human Rights</i> .....	13
ADELE EMILIA CATERINI, <i>Green Financial Instruments: ‘Ecological’ Patrimoniality and ‘Social’ Obligatory Relationships</i> .....	41
GIOVANNI RUSSO, <i>Freedom of Economic Initiative and ESG Parameters. Towards a New Corporate Social Responsibility</i> .....	57
GIANNA GIARDINI, <i>The Involvement of Third Parties in Sustainable Contracting Processes</i> .....	73
DAVIDE CASTAGNO AND MARIA PIA GASPERINI, <i>Procedural Hurdles of Climate Change Litigation in Italy: Prospects in Light of the ECtHR Decision in the KlimaSeniorinnen Case</i> .....	91
IVAN LIBERO NOCERA, <i>The Entrepreneurial Nature of Renewable Energy Communities and Distribution of Incentives</i> .....	109
MANUELA GIOBBI, <i>The Impact of Contractual Energy Sustainability on Vulnerable Persons and on Market Regulation</i> .....	125
SARA ZUCCARINO, <i>The Italian-European Ecological Dimension as a Guiding Criterion for All Human Activity. Cues in Pharmaceutical Activity</i> .....	141
MARIA FRANCESCA LUCENTE, <i>Sustainable Drug Production and Consumption: Legal Profiles</i> .....	159

FEDERICA LAURA MAGGIO, <i>EU Pharma Legislation Reform: Balancing Marketing Authorization, Environmental Risk Assessment, and IP Protection for Enhanced Innovation and Green Transition</i> .....	177
KARINA ZABRODINA, <i>The Energy Performance of Mixed-use Buildings in Italy and in the United States. Treatment Criteria and Tools for Financing Energy Adaptation</i> .....	195
MANUEL IGNACIO FELIU REY, <i>Toward a New and Sustainable Era of the Building Sector: Building Information Modelling (BIM)</i> .....	211
ART NASH AND GIANNA GIARDINI, <i>Negative Externalities from Electricity Generation and the Right Remedy: A Comparative Analysis of Alaska and Sweden</i> .....	225
KOZUE KASHIWAZAKI, <i>Circulative Bottom-Up Processes for Sustainable Development as a Prosumer: Lesson Learned from Asia</i> .....	243
RICCARDO PERONA, <i>Reframing Legal Pathways to Sustainable Transition: A European Perspective on Ecological Constitutionalism in Light of the Cauca River Case in Colombia</i> .....	263
ELISABETTA CERONI, <i>The Use of Fiscal Levers to Foster Green Communities: US and EU Strategies</i> .....	283

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# The Italian-European Ecological Dimension as a Guiding Criterion for All Human Activity. Cues in Pharmaceutical Activity

Sara Zuccarino\*

## Abstract

The essay analyses the ecological inspiration behind Italian-European legislation. Environmental protection is a principle that shapes every human activity with the aim of enhancing the welfare levels of society. This reversal of values associated with this approach is examined with particular reference to the pharmaceutical sector.

## Keywords

Sustainable Transition, Constitutional Biocentrism, Personalism, Green Pharmaceutical Strategy, Environmental Risk Assessment, Pharmaceutical Consumer.

## I. Introduction

The ecological emergency – the mantra of our times – makes it imperative to reinterpret legal and economic paradigms in light of sustainable development,<sup>1</sup> ie, development that is capable of balancing, in a harmonious manner, the ecosystem with economic rationality.<sup>2</sup> The effective realization of our scale of values, inspired

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<sup>1</sup> The notion of sustainable development dates back 40 years. It is contained in the Brundtland Report of the World Commission on Environment and Development (WCED) 'Our Common Future', which defines 'sustainable': 'development that meets the needs of the present generation without compromising the ability of future generations to meet their own needs'. The World Commission on Environment and Development, *Our Common Future* (Oxford: Oxford University Press, 1987), 16. See, M. Redclift, 'Sustainable development (1987-2005): An Oxymoron Comes of Age' *Sustainable Development*, 212-227 (2005).

<sup>2</sup> European Parliament and Council Decision 1386/2013/EU of 20 November 2013 on a General Union Environment Action Programme to 2020 (7<sup>th</sup> EAP) 'Living well, within the limits of our planet' [2013] OJ L354/171. See B. Sjøfjell and C. Bruner eds, 'Corporation and Sustainability', in *Cambridge Handbook of Corporate Law, Corporate Governance and Sustainability* (Cambridge: Cambridge University Press, 2019), chapter 1; L. Strine, 'Toward Fair and Sustainable Capitalism' *Harvard John M. Olin Discussion Paper* no 1018, available at [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=24361924](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=24361924) (last visited 23 September 2023).



by personalism and solidarism, presupposes an ‘integral ecological dimension’, ie, an inseparable symbiosis between environmental and human ecology.<sup>3</sup> In this perspective, sustainability must be reconstructed as a cardinal principle of our legal system and, therefore, as a component of public order.<sup>4</sup> It becomes a hermeneutic canon both for both the legitimacy (constitutional, European, and international) of regulatory acts and the worthiness<sup>5</sup> of legal relations. In particular, the principle *de quo* – in conforming, planning and controlling ‘every legally relevant human activity’ – ensures that any form of autonomy (legislative, administrative, and private) is directed toward the protection of the environment, also ‘to guarantee that the satisfaction of the needs of present generations cannot compromise the quality of life and the possibility of future generations’.<sup>6</sup> In the functional dimension envisaged, the *jus-generative* force of the principle of sustainability emerges, insofar as it is capable of regulating concrete events, appropriately balanced with other conflicting principles and rights.<sup>7</sup>

<sup>3</sup> F. Parente, *Territorio ed eco-diritto: dall’ecologia ambientale all’ecologia umana* (Napoli: Edizioni Scientifiche Italiane, 2022), 9, 47; D.R. Boyd, ‘Constitutions, Human Rights and the Environment: National Approaches’, in *Research Handbook on Human Rights and the Environment* (Cheltenham-Northampton: Edward Elgar Publishing, 2015), 170-199.

<sup>4</sup> It is worth marking the unity of the concept of public order based on the protection of the person and the fallacy of the expression ‘ecological public order’. On this point, 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), 321-331. In general, on public order as a historical concept, influenced by the social and cultural evolution of a country, G. Perlingieri, ‘In tema di ordine pubblico’ *Rassegna di diritto civile*, 1382, 1384-1385 (2021). The author points out that public order is a dynamic concept that is an expression of a country’s values. ‘These have a hierarchy, they are not irreconcilable monads and, once positioned in principles (and rules), far from being absolute, eternal, transcendent or metaphysical, they are, like every norm, an affair of men and, as such, historical and relative, susceptible to being balanced and balanced in such a way as to support instances of openness to globalisation and, at the same time, preserve cultural and constitutional identity’. The English translation of the original text is provided by the author of this essay.

<sup>5</sup> A. Lasso, ‘Sostenibilità sociale e diritti fondamentali della persona’, in D.A. Benitez and C. Fava eds, *Sostenibilità: sfida o presupposto?* (Padova: Cedam, 2019), 92, 113.

<sup>6</sup> The words in inverted commas refer to Art 3 *quater*, decreto legislativo 3 April 2006 no 152, ‘Environment Code’. The concepts expressed in the text were inspired by the pages of P. Perlingieri, ‘Produzione, beni e benessere’, in *Benessere e regole dei rapporti civili. Lo sviluppo oltre la crisi. Atti di 9° Convegno Nazionale SISDiC, 8-9-10 maggio* (Napoli: Edizioni Scientifiche Italiane, 2015), 510-511.

<sup>7</sup> N. Lipari, *Vivere il Diritto* (Napoli: Edizioni Scientifiche Italiane, 2023), 67. The author points out that: ‘In the season of postmodernism, which is connoted by a non-homologous multiplicity, the rule enters into dialectics with chance and from this it often

It is worth highlighting that the environmental matter, which is the specific focus of this discussion, determines the abandonment of top-down laws, characterised by rigid and detailed regulations, which are, among other things, prone to rapid obsolescence. Instead, we are witnessing the emergence of a right *ex parte societatis* that is based on principles that, albeit of different rank and origin, are destined to merge – in an open legal system such as the Italian one – into constitutional legality.<sup>8</sup>

There is no doubt that legislation by principles, accompanied by an axiological interpretation, can further the realization of the goals set by the sustainable transition.<sup>9</sup>

The logical corollary of this statement is the abandonment of a theory of interpretation, *sub specie aeternitatis*, based on the mechanism of punctilious and specific regulation and the logical scheme of syllogistic subsumption. Legal interpretation becomes primarily systematic and axiological, ie, referring to the values of the system.<sup>10</sup> In this context, the jurist's task is to (re)read the rules in light of constitutional and European principles to identify the regulation of the concrete case that is as close as possible to the overall logic of the legal system in force.

In a nutshell, in the geological era of the Anthropocene<sup>11</sup>, the polymorphic<sup>12</sup> principle of sustainability operates as an organizing

draws the guiding criteria for its own formulation'. The English translation of the original text is provided by the author of this essay.

<sup>8</sup> *ibid* 121-137.

<sup>9</sup> E. Caterini, *Sostenibilità e ordinamento civile* (Napoli: Edizioni Scientifiche Italiane, 2018), 91; M. Pennasilico, 'Sviluppo sostenibile, legalità costituzionale e analisi "ecologica" del contratto' *Persona e mercato*, 37 (2015); J. Ebbesson and E. Hey, *The Cambridge Handbook of Sustainable Development Goals and International Law* (Cambridge: Cambridge University Press, 2022), 1-50.

<sup>10</sup> P. Perlingieri, n 6 above, 512-516.

<sup>11</sup> This concept is underlined by M. Lim, *Charting Environmental Law Futures in the Anthropocene* (Cham: Springer, 2019), 20; C.P. Krieg and P. Minoia, 'Anthropocene Conjunctures', in C.P. Krieg and R. Toivanen eds, *Situating Sustainability: A Handbook of Contexts and Concepts* (Helsinki: Helsinki University Press, 2021), 39- 50; M. Harm Benson and R. Kundis Craig, *The End of Sustainability: Resilience and the Future of Environmental Governance in the Anthropocene* (Kansas: University Press of Kansas, 2017), 1-21.

<sup>12</sup> On the configuration of sustainability from an environmental, economic, and social perspective, see M. Pennasilico, 'La "sostenibilità ambientale" nella dimensione civil-costituzionale: verso un diritto dello "sviluppo umano ed ecologico"' *Rivista quadrimestrale di diritto dell'ambiente*, 1, 7-8 (2020); Id, 'L'insegnamento del diritto privato tra modello tradizionale e problematiche attuali (Manifesto per un diritto privato ecosostenibile)' *Rassegna di diritto civile*, 641, 661 (2019).

criterion for the thinking and functioning of social and economic systems to ensure ‘global well-being’.<sup>13</sup>

Starting from these premises, this study focuses on the theme of environmental sustainability with particular attention to the pharmaceutical sector. It aims to demonstrate that environmental considerations shape the discipline and direct production processes so that they realize, in compliance with the so-called ‘planetary limits’,<sup>14</sup> the axiology of the legal system.

## II. The Era of ‘Constitutional Biocentrism’

The environmental dimension finds its regulatory entanglements in the complex<sup>15</sup> and unitary Italian-European source system.<sup>16</sup> This framework underscores the tendency of legislators, both domestic and European, to orient their activities toward ecological considerations.<sup>17</sup> While it is beyond the scope of this work to catalogue the extensive legislation on the subject, it is worth dwelling on the norms of the Italian Constitution and the

<sup>13</sup> E. Caterini, ‘Iniziativa economica privata e «crisi ecologica». Interpretazione anagogica e positivismo’, in G. Perlingieri and E. Giorgini eds, *Diritto europeo e legalità costituzionale a trent’anni dal volume di Pietro Perlingieri* (Napoli: Edizioni Scientifiche Italiane, 2024), 290; P. Perlingieri, n 6 above, 510-511; P. Jain and Pra. Jain, ‘Are the Sustainable Development Goals really sustainable? A Policy Perspective’, in *Sustainable Development* (New York: John Wiley & Sons Ltd, 2020), 28, 1642-1651.

<sup>14</sup> F. Parente, n 3 above, 15. On the concept of ‘planetary boundaries’ see, most recently, European Parliament and Council Decision 2022/591/EU of 6 April 2022, on a General Union Environment Action Programme to 2030 (8<sup>th</sup> EAP). This document, in prescribing the priorities of European policy, states in Art 2: ‘The 8th EAP shall have the long-term priority objective that by 2050 at the latest, people live well, within the planetary boundaries in a well-being economy where nothing is wasted, growth is regenerative, climate neutrality in the Union has been achieved and inequalities have been significantly reduced. A healthy environment underpins the well-being of all people and is an environment in which biodiversity is conserved, ecosystems thrive, and nature is protected and restored, leading to increased resilience to climate change, weather- and climate-related disasters and other environmental risks. The Union sets the pace for ensuring the prosperity of present and future generations globally, guided by intergenerational responsibility’, European Parliament and Council Decision 2022/591/EU of 6 April 2022, on a General Union Environment Action Programme to 2030 [2022] OJ L 114/22.

<sup>15</sup> P. Perlingieri, *Il diritto civile nella legalità costituzionale secondo il sistema italo-europeo delle fonti, Fonti e interpretazione* (Napoli: Edizioni Scientifiche Italiane, 4<sup>th</sup> ed, 2020), II, 59-69.

<sup>16</sup> P. Perlingieri, ‘I valori e il sistema ordinamentale «aperto»’ *Rassegna di diritto civile*, 1-9 (2014); Id, ‘Interpretazione e controllo di conformità’ *Rassegna di diritto civile*, 593, 595 (2018).

<sup>17</sup> A.P. Singh, ‘Towards the environmental state: revelations from a design-oriented enquiry of environmental constitutionalism’ 25 *Environmental Law Review*, 120-134 (2023).

European Treaties. These documents explicitly recognize the environmental interest as a necessary evaluative factor for both public authorities and private activities.

The principle of sustainable development appears to be deeply rooted in our constitutional system. It is not only explicitly provided for by both supranational and national provisions but it is also immanent and closely connected to the value of the individual and, therefore, to other principles of constitutional significance.<sup>18</sup> There is no doubt, for instance, that ‘ecological necessity’ reinforces the set of duties of solidarity prescribed by Art 2 of the Constitution.<sup>19</sup> As will be further discussed in the following pages, fulfilling the duty of *environmental solidarity* is the basis for the effective realization of the constitutional programme aimed at the development of the individual.<sup>20</sup> The evolutionary interpretation<sup>21</sup> of Art 2 of the Constitution, for example, allows for the extension of the protection of inviolable human rights to include the right of future generations to live in a healthy environment. Additionally, it establishes the foundation for intergenerational responsibility among human beings.<sup>22</sup> In this trajectory, legal reasoning opens up to an intertemporal dimension, capable of ensuring, at the moment of application, the complementarity between the inviolable rights of future generations and the non-derogable duties of present generations.

<sup>18</sup> P. Perlingieri, *Il diritto civile nella legalità costituzionale secondo il sistema italo-europeo delle fonti, Situazioni soggettive* (Napoli: Edizioni Scientifiche Italiane, 4<sup>th</sup> ed, 2020), III, 83; Id, ‘Principio personalista, dignità umana e rapporti civili’ *Annali della Società italiana degli Studiosi del Diritto Civile*, 1-5 (2020).

<sup>19</sup> R.L. Lorenzetti and P. Lorenzetti, *Diritto ambientale* (Napoli: Edizioni Scientifiche Italiane, 2020), 19. On the intergenerational relationship, interesting insights are drawn from the ruling of the Bundesverfassungsgericht, Order of 24 March 2021, 1 BvR 2656/18. The decision affirms the constitutional illegitimacy of the Federal Climate Protection Act insofar as it does not sufficiently protect people from future reductions in their rights that may become necessary as climate change progresses. More precisely, the federal law, by postponing most of the urgent and relevant measures beyond 2030, risks disproportionately shifting the burden of reducing greenhouse gas emissions onto future generations, leading to disproportionate losses of freedom between generations.

<sup>20</sup> B. Borrillo, ‘Spunti in tema di sostenibilità, categorie civilistiche e rivoluzione digitale’ *Tecnologie e diritti*, 13, 19 (2024).

<sup>21</sup> Interpretation must adapt to the ‘dynamism of social reality’ since ‘even the provision that remains intact over time changes its meanings due to normative and factual changes (economic, social, cultural circumstances)’. Thus P. Perlingieri, n 14 above, 378.

<sup>22</sup> M. Pennasilico, n 11 above, 22.

The environmental dimension of our legal system was explicitly affirmed by the constitutional reform of 2022<sup>23</sup> which amended Arts 9 and 41. More precisely, Art 9, para 3, prescribes, among the fundamental principles, that of the ‘utilization of the environment, biodiversity and ecosystems, also in the interest of future generations’.<sup>24</sup> In other words, the legal system is committed to protecting the environment in its various biological manifestations. There is, in fact, an awareness of the close scientific and functional interconnection between the triad ‘environment, biodiversity, and ecosystems’.<sup>25</sup>

Art 41 of the Constitution states that: ‘1. Private economic initiative is free. It may not be carried out in conflict with social utility or in such a way as to be harmful to health, the environment, security, liberty or human dignity. 3. The law determines the appropriate programmes and controls so that public and private economic activity may be directed and coordinated for social and environmental purposes’. The introduction of the word ‘environment’ in the text allows social utility to be interpreted from an ecological perspective. Thus, the monitoring of a company’s environmental impact cannot be considered an exceptional and external limitation, but rather a ‘consubstantial’ way of being. Ecological value shapes every economic activity.<sup>26</sup> Accordingly, economic activities must not be carried out in such a way as to harm health, the environment, safety, freedom and human dignity. Besides, they must pursue environmental value because this is what is required to operate without conflict with social-ecological utility.

The reform of Arts 9 and 41, while making explicit what was already implicit in the previous regulatory framework, intended to emphasize the impact of environmental protection on legal relations and its close correlation with the human person.<sup>27</sup> Indeed, one of the most relevant aspects of the full development of the

<sup>23</sup> Legge costituzionale 11 February 2022 no 1; on the advisability or otherwise on the constitutional reform, see R. Landi, *Risanamento ambientale e vicende della proprietà* (Napoli: Edizioni Scientifiche Italiane, 2022), 51.

<sup>24</sup> M. Cecchetti, ‘La revisione degli articoli 9 e 41 della Costituzione e il valore costituzionale dell’ambiente: tra rischi scongiurati, qualche virtuosità (anche innovativa) e molte lacune’, in Id, L. Ronchetti and E. Bruti Liberati eds, *Tutela dell’ambiente: diritti e politiche* (Napoli: Edizioni Scientifiche Italiane, 2021), 41.

<sup>25</sup> The Constitutional Court had emphasised, even before the reform, the reconstruction of the environment as a unitary albeit complex ‘good’. See, *ex multis*, Corte costituzionale 7 November 2007 no 367.

<sup>26</sup> L. Ruggeri, ‘Ambiente e tecnologie: nuove sfide per la tutela della persona’ *ambientediritto.it*, 8 (2023).

<sup>27</sup> On the constitutional reform discussed in the text, see E. Jona, ‘La libertà di iniziativa economica e la protezione dell’ambiente e della salute’ *federalismi.it*, 2 (2023).

human person is, pursuant to Art 4 of the Constitution, ‘the material and spiritual progress of society’, which cannot be achieved in an unhealthy habitat. This perspective has always guided the jurisprudence of the Italian Constitutional Court which, on several occasions prior to the 2022 reform, qualified the environment as a fundamental right of the human person and a founding element of the entire *societas*.<sup>28</sup>

### III. The European Regulatory Framework

The axiological pre-eminence accorded to the person and their effective protection also inspired the European legislator.<sup>29</sup> This concept is well articulated by the President of the European Commission, Ursula Von der Leyen, who, in presenting the European Green Deal, specified that the Union’s policy aims at ‘reconciling the economy with our planet’.<sup>30</sup> The objective is to balance the needs of technological and economic development, both unstoppable and uncontainable, with respect for the value of the human person in their existential-environmental context.<sup>31</sup> This

<sup>28</sup> Since the 1980s, through an evolutionary interpretation of Arts 2, 9 and 32 of the Constitution, the Court has configured the environment as a ‘constitutional value’. *Ex multis*, Corte costituzionale 30 December 1987 no 641; 16 March 1990 no 127; 29 May 2005 no 62; 7 October 2016 no 216. In these pronouncements, the Court defines environmental protection as a value that is configured as a synthesis, in a global or integrated vision, of a plurality of aspects and a series of other values that pertain not only to merely naturalistic or health interests but also to cultural, educational, recreational and participatory interests, all characterized by the essential importance they hold for the life of the community.

<sup>29</sup> T. Etty and H. Somsen, *The Yearbook of European Environmental Law* (Oxford: Oxford University Press, 2008), VIII; PM. Hedemann-Robinson, *Enforcement of European Union Environmental Law. Legal Issues and Challenges* (Abingdon: Routledge, 2<sup>nd</sup> ed, 2015), 1-20. For further remarks in this direction see also: S. Bookman, ‘Demystifying environmental constitutionalism’ 54 *Environmental Law*, 1-77 (2024); J.P. Balkenende and G. Buijs, *Capitalism Reconnected: Toward a Sustainable, Inclusive and Innovative Market Economy in Europe* (Amsterdam: University Press, 2024), 195-224.

<sup>30</sup> European Commission, Communication to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of Regions, of 11 December 2019 on ‘The European Green Deal’ COM(2019) 640.

<sup>31</sup> On this point, interesting insights are drawn from the jurisprudential approach of the Italian Constitutional Court and the Court of Justice on the well-known *Ilva* case. Corte costituzionale 9 May 2013 no 85; Eur. Court H.R., *Cordella v Italy*, App no 54414, Judgment of 24 January 2019; *Ardimento et al v Italy*, App no 4642, Judgment of 5 May 2022. The aforementioned pronouncements make it clear that safeguarding the continuity of production in strategic sectors for the national economy does not mean undermining rights such as the protection of health and the environment. To avoid the ‘exclusive’ assertion of one right over others, it is necessary to proceed to a reasonable and

approach is grounded in primary sources. Pursuant to Arts 191-193 of the Treaty on the Functioning of the European Union (TFEU), the Union promotes a policy of ‘preserving, protecting and improving the quality of the environment’, ‘protecting human health’, ‘prudent and rational utilization of natural resources’, and ‘promoting measures at international level to deal with regional or worldwide environmental problems, and in particular to combat climate change’ (Art 191, para 1 TFEU).

In support of the approach described above, it is noted that the Treaty on European Union (TEU) includes among the objectives of EU policy, in compliance with internationally binding commitments,<sup>32</sup> the promotion of balanced and sustainable economic and social progress. To this end, Art 3, para 3, requires the Union to strive for sustainable development ‘based on balanced economic growth [...], a highly competitive social market economy [...] and a high level of protection and improvement of the quality of the environment’.<sup>33</sup> Arts 11 TFEU<sup>34</sup> and 37 of the Charter of Fundamental Rights of the European Union<sup>35</sup> also point in this direction, reflecting Europe’s commitment to ‘requirements related to the protection of the environment’.

Starting from these normative premises, it is clear that sustainable development is placed at the centre of the EU’s values

proportionate balancing of legal values. Thus P. Perlingieri, ‘Dittatura del relativismo e ‘Tirannia dei valori’, in T.G. Tasso ed, *Fatto e diritto. L’ordinamento tra realtà e norma* (Napoli: Edizioni Scientifiche Italiane, 2012), 127-130; Id, *Il diritto civile nella legalità costituzionale secondo il sistema italo-europeo delle fonti. Attività e responsabilità* (Napoli: Edizioni Scientifiche Italiane, 4<sup>th</sup> ed, 2020), IV, 262. The author emphasises that, in our legal system, fundamental rights are in a relationship of mutual integration, and it is not possible to consider one prevailing, in an absolute sense, over the other. A different approach would entail the unlimited expansion of one of the rights, which would become a tyrant against the other constitutionally recognised and protected legal situations.

<sup>32</sup> It is not possible here to go over the extensive international legislation even in passing. However, it should be emphasized that openness on the part of the domestic and European systems is essential because solutions to the environmental problem must be thought of from a global perspective.

<sup>33</sup> For an analysis of the concept of social market economy closely related to sustainable development, please refer to S. Zuccarino, *Il contratto ‘conformato’ quale statuto normativo del mercato energetico* (Napoli: Edizioni Scientifiche Italiane, 2021), 42-60 and bibliography cited therein.

<sup>34</sup> This Article states that: ‘Environmental protection requirements must be integrated into the definition and implementation of the Union’s policies and activities, in particular with a view to promoting sustainable development’, Consolidated version of the Treaty on the Functioning of the European Union [2016] OJ C202/53.

<sup>35</sup> In that standard we can read that: ‘A high level of environmental protection and the improvement of the quality of the environment must be integrated into the policies of the Union and ensured in accordance with the principle of sustainable development’, Charter of Fundamental Rights of the European Union [2012] OJ C326/17.

and constitutes the *humus* of a modern notion of public order to which the European policy and the entire legal system must conform.<sup>36</sup> In this context, in axiologically orienting the regulatory activity of the European Union, sustainable development becomes an evaluative parameter of the actions of public and private subjects.<sup>37</sup>

As evidenced by the regulatory analysis just conducted, sustainability is not a vague or abstract concept but rather one that expresses a high degree of normativity and significant axiological power.<sup>38</sup>

The European environmental principles – not only that of sustainable development but also those indicated in Art 191, para 2 TFEU<sup>39</sup> – are integrated into our legal system which, pursuant to Arts 11 and 117, para 1 of the Constitution, is open to the ‘constraints deriving from *the* community system and international obligations’. The aforementioned provisions allow supranational principles to enter our legal system, making them directly applicable norms that influence both public authority and the fabric of private autonomy, in a manner consistent with the systematic and axiological method.<sup>40</sup>

<sup>36</sup> Thus, P. Perlingieri, ‘Relazione conclusiva’, in P. D’Addino ed, *Mercato ed etica* (Napoli: Edizioni Scientifiche Italiane, 2009), 328; Id, ‘Diritto dei contratti e dei mercati’ *Rassegna di diritto civile*, 878 (2011) who, in recalling Art 1, paras 3 and 4 of the Lisbon Treaty, points to the reversal of course made by the European Union, aimed at emphasizing the relevance of the market as an instrument for the settlement of different interests in a solidaristic matrix.

<sup>37</sup> On this point, see R. Pepper and H. Hobbs, ‘The Environment Is All Rights: Human Rights, Constitutional Rights and Environmental Rights’ 44 *Melbourne University Law Review*, 634 (2020).

<sup>38</sup> On this point, see the pages of G. Perlingieri, ‘«Sostenibilità», ordinamento giuridico e «retorica dei diritti». A margine di un recente libro’ *Foro napoletano*, 101 (2020); P. Perlingieri, n 4 above, 322, who points out that: ‘[w]hile the development of a country is not given by the GDP (according to an accountancy, economic conception of social and human relations), but depends on the degree of realisation of the wellbeing and quality of life of human beings, development is sustainable when it guarantees the full and free development of the human person’.

<sup>39</sup> The quoted provision states that the Union's policy shall be based on ‘the precautionary principle and the principle that preventive action should be taken, the principle that environmental damage should as a priority be rectified at source and the polluter should pay’. For a deeper analysis of the aforementioned principles, see M. Pennasilico, n 11 above, 15 and the bibliography cited therein.

<sup>40</sup> M. Pennasilico, n 4 above, 293, 294. For the sake of completeness, we cannot overlook the fact that part of the doctrine questions the preceptive aspect or direct applicability of environmental principles also to inter-private relations. There are those who maintain that the environmental principles produce generic obligations of conformation for the European institutions alone. It is excluded that they can be invoked as a direct and immediate source of enforceable rights *erga omnes*, or that obligations and burdens can derive from them for individual European citizens.



In other words, the European environmental principles become substantive legal norms that enrich and modernize the jurist's toolkit<sup>41</sup> and help him in his balancing act between economic efficiency, albeit fundamental, and respect for the human person.<sup>42</sup>

In conclusion, the environment emerges as an axiological element conforming to the dynamics of the market and juridicity to realize the principle of sustainable development, which serves as the paradigm of progress in post-modern society.<sup>43</sup>

#### **IV. The Ecological Dimension from the Perspective of Personalism**

Within the framework outlined in the preceding paragraphs, the doctrine that advocates for an interpretation of sustainable development, in a personalistic and solidaristic manner, ie, with respect for human rights, is commendable.<sup>44</sup> The pre-eminence of the personalist function over the mercantile and patrimonialist one is argued.<sup>45</sup> It is undeniable that the dignity of the person, as the

<sup>41</sup> P. Perlingieri, 'Scuole civilistiche e dibattito ideologico: introduzione allo studio del diritto privato in Italia', in Id, *Scuole, tendenze e metodi. Problemi del diritto civile* (Napoli: Edizioni Scientifiche Italiane, 1989), 75; Id, *Il diritto civile nella legalità costituzionale secondo il sistema italo-europeo delle fonti. Metodi e tecniche* (Napoli: Edizioni Scientifiche Italiane, 4<sup>th</sup> ed, 2020), I, 37.

<sup>42</sup> On the sources of European law, see N. Lipari, 'Il problema dell'effettività del diritto comunitario', in *Diritto comunitario e sistemi nazionali: pluralità delle fonti e unitarietà degli ordinamenti. Atti del 4° Convegno Nazionale SISDiC, 16, 17, 18 Aprile 2009* (Napoli: Edizioni Scientifiche Italiane, 2010), 633; 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), 117, 132; P. Perlingieri, n 6 above, 518; A. Zoppini, 'Il diritto privato e le "libertà fondamentali" dell'Unione europea. (Principi e problemi della *Drittwirkung* nel mercato unico)', in F. Mezzanotte ed, *Le "libertà fondamentali" dell'Unione europea e il diritto privato* (Rome: Roma-Tre Press, 2016). The author focuses on the direct application of the Treaty rules to the regulation of private relationships.

<sup>43</sup> K. Hawkins, *Environmental and Enforcement: Regulation and Social Definition of Pollution* (Oxford: Oxford University Press, 1984). On the relevance of environmental sustainability as a value of the Italian-European legal system, the study by M. Pennasilico, n 11 above, 17, is indispensable. The author, in proceeding to a reading of current constitutional legality in light of the relevance of sustainable development, promotes an ecological turnaround.

<sup>44</sup> P. Perlingieri, *Il diritto civile*, n 17 above, 77.

<sup>45</sup> G. Perlingieri, n 35 above, 102. On this point see also F. Bertelli, *Profili civilistici del "Dieselgate"* (Napoli: Edizioni Scientifiche Italiane, 2021), 176.

cornerstone of human rights and personalism, fundamentally shapes the concept of sustainable development.<sup>46</sup>

In light of this approach, it can be argued that the principle of sustainability, precisely because it is fundamental to the individual, constitutes a core element of our constitutional legality. It should be considered, on the one hand, as a rule directly applicable to inter-individual relations, regardless of the existence of a related subjective right and, on the other, as a priority consideration in the balancing of principles.<sup>47</sup> Only in this way can a reasonable and proportionate weighing of all the instances involved in the concrete case be achieved.

In other words, while the environment must be balanced with other interests, it is also true that its priority is underscored by the recognition that the ecological crisis has reached such a level where it would be unreasonable to treat ecological value as secondary. In fact, if the environment constitutes the biological foundation for the existence of every form of life, including human life, it must be regarded as an inviolable value and, as such, exempt from any compromise.<sup>48</sup> In short, it is the very survival of humanity that requires ecological concerns to be placed at the centre of the social, economic, political, cultural, and spiritual dimensions of human life.<sup>49</sup> Consequently, the relationship between the economy, nature, and man must be understood in a circular manner, with its beginning and its end centred on the person, the ecosystem's purpose and value.<sup>50</sup>

<sup>46</sup> P. Perlingieri, n 6 above, 510; M. Francesca, 'Acqua bene comune: la difficile convivenza di teorie e fatti' *Rassegna di diritto civile*, 555, 558 (2022). In this sense, see the economic analysis carried out by A. Sen, *Lo sviluppo è libertà. Perché non c'è crescita senza democrazia*, translated by G. Rigamonti (Milano: Mondadori, 2000), *passim*. The author argues the need to decouple the economic evaluation of development from GDP in order to focus on a development capable of guaranteeing the free and full development of the person; a development that is based on the elimination of illiberal factors, such as hunger, poverty, illiteracy, lack of health care and environmental protection.

<sup>47</sup> M. Pennasilico, 'Ambiente e iniziativa economica: quale bilanciamento?' *Le nuove leggi civili commentate*, 48, 51 (2024).

<sup>48</sup> M. Pennasilico, 'Sviluppo sostenibile e solidarietà ambientale', in Id ed, *Manuale di diritto civile dell'ambiente* (Napoli: Edizioni Scientifiche Italiane, 2014), 42. The author criticizes the Constitutional Court's sentence no 85 of 9 May 2013 on the *Ilva* case. The Strasbourg Court also intervened on this point, condemning the Italian State, pursuant to Art 8 of the European Convention on Human Rights, for failing to protect the life and health of the applicants and their families (n 28 above). The European Court of Human Rights was also, in the same vein, condemning the Italian Republic for failing to respect and adjust the air pollution values in some areas of the country as soon as possible (Case C-644/18 *European Commission v Italian Republic*, Judgment of 10 November 2020).

<sup>49</sup> E. Caterini, n 12 above, 283; M. Pennasilico, n 45 above, 49.

<sup>50</sup> E. Caterini, n 12 above, 286.

## V. The Environmental Paradigm as the Key to a ‘Green’ Pharmaceutical Strategy

The Italian-European environmental principles resonate strongly within the pharmaceutical sector which is well known for its significant social and environmental impact.<sup>51</sup> The research and production process of a drug, in fact, requires substantial resources (principally energy and water) and generates, in turn, large quantities of waste that need careful management in order not to compromise the very health that these products are supposed to improve. In 2020, with an incomprehensible and unforgivable delay, the EU defined its pharmaceutical strategy,<sup>52</sup> aiming to balance the competitiveness and innovation capacity of this strategic sector with its environmental and social sustainability.<sup>53</sup> The reform under consideration confirms the need to resize an economic approach that traditionally characterizes production activities, promoting instead a perspective that respects both individuals and their *habitat*, which, as previously stated, constitutes the foundation of Italian-European constitutionalism.<sup>54</sup>

The goal is ambitious, aiming to overhaul the processes and methods of medicine production, distribution, usage, and disposal, aligning them with the principles of the circular economy. This includes adapting to scientific and technological changes, promoting the role of the responsible consumer, and ensuring proper disposal practices. This reflects a gradual shift from a traditional economy to a green-economy and blue-economy that commits all companies to preserving the environment.

<sup>51</sup> The concept is clearly illustrated by S. Walter and K. Mitkidis, ‘The Risk Assessment of Pharmaceuticals in the Environment’ 9 *European Journal of Risk Regulation*, 527-547 (2018); E. Cavallin, ‘Preventing Pandemics by Building Bridges in EU Policy and Law’ 30 *European Energy and Environmental Law Review*, 162-194 (2021).

<sup>52</sup> European Commission, Communication to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, ‘Pharmaceutical Strategy for Europe’ COM(2020) 761 final.

<sup>53</sup> J. Drexler and N. Lee eds, *Pharmaceutical Innovation, Competition and Patent Law. A Trilateral Perspective* (Cheltenham-Northampton: Edward Elgar Publishing, 2013); T.K. Hervey and J.V. Mchale, *European Union Health Law. Themes and Implications* (Cambridge: Cambridge University Press, 2015); P. Figueroa and A. Guerrero eds, *EU Law of Competition and Trade in the Pharmaceutical Sector* (Cheltenham-Northampton: Edward Elgar Publishing, 2019); D.W. Hull and M.J. Clancy, ‘The Application of EU Competition Law in the Pharmaceutical Sector’ *Journal of European Competition Law & Practice*, 646-659 (2019).

<sup>54</sup> P. Perlingieri, *La personalità umana nell’ordinamento giuridico* (Napoli-Camerino: Edizioni Scientifiche Italiane, 1972), 417; Id, ‘Principio personalista, dignità umana e rapporti civili’ *Annali della Società italiana degli Studiosi del Diritto Civile*, 1-5 (2020).

The path begun in 2020 culminated in 2023 with the proposal for a directive on a Union code relating to medicinal products for human use, COM(2023) 192,<sup>55</sup> and a regulation laying down Union procedures for the authorization and supervision of medicinal products for human use and defining the rules governing the European Medicines Agency (EMA), COM(2023) 193.<sup>56</sup> In particular, it is intended to create, also in the light of the principle of subsidiarity,<sup>57</sup> a shared regulation of pharmaceuticals that upholds ecological values. Certainly, the answer to a global issue, such as the environment, cannot be delegated to autonomous and varied choices of sovereign entities. Such an approach would only increase the fragmentation of legal regulations, undermining regulatory certainty and a level playing field in competition between economic operators within the European market.

The review of the pharmaceutical activity with a focus on environmental and ecosystem protection confirms the EU's objective to carve out a role for itself as a world leader in sustainability, in light of Art 3, para 5 TEU in which we can read that: 'In its relations with the wider world, the Union shall uphold and promote its values and interests [...]. It shall contribute [...] to the sustainable development of the Earth'. In pursuing these aims, the European institutions shall, with due regard for the principles of equality and solidarity, work out multilateral solutions to 'foster the sustainable development of developing countries in economic, social and environmental terms, with the primary aim of eradicating poverty' (Art 21, para 2, letter d) and 'preserve and improve the quality of the environment and the sustainable

<sup>55</sup> Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC.

<sup>56</sup> Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorization and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006.

<sup>57</sup> Art 5, para 3 TEU stipulates that: 'in areas which do not fall within its exclusive competence, the Union shall take action only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central level or at regional or local level, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level'. On the principle of subsidiarity, see K.V. Kersbergen and B. Verbeek, 'The Politics of Subsidiarity in the European Union' *Journal of Common Market Studies*, 32, 215-236 (1994); N.M de Sadeleer, 'Principle of Subsidiarity and the EU Environmental Policy' *Journal of European Environmental & Planning Law*, 9, 63-70 (2012); A. Follesdal, 'The Principle of Subsidiarity as a Constitutional Principle in International Law' *Global Constitutionalism*, 2, 37-62 (2013).

management of the world's natural resources' (Art 21, para 2, letter f).<sup>58</sup> For example, the partnership between the European Union and the African Union aims to promote the creation of the African Medicines Agency and to obtain a harmonised regulatory system for the pharmaceutical industry.<sup>59</sup>

## **VI. Environmental Risk Assessment as a Prerequisite for Marketing Authorization of a Drug**

Delving into specifics, the environmental perspective emerges is prominently reinforced by the strengthened Environmental Risk Assessment (ERA) requirements for the marketing authorization of a drug. The environmental risk assessment has been mandatory for the sector under review since 2005.<sup>60</sup> It is intended to detail the life cycle of the product. The company applying for authorization must, in fact, specify: the raw materials used and their degree of toxicity to plants, animals, and micro-organisms, considering the duration of their persistence in the environment; the packaging envisaged and the environmental impact of transport; and the disposal and/or recycling procedures. The applicant must also indicate any environmental risk mitigation measures taken.<sup>61</sup>

The intention of the European legislator is to establish the ERA as a prerequisite for obtaining marketing authorization for a particular medicinal product.<sup>62</sup> Arts 15, para 1, letter d) COM(2023)

<sup>58</sup> It is worth noting that the European pharmaceutical industry is almost entirely dependent on third countries. For example, India is a low-cost production destination for multinational pharmaceutical companies. This has led to an acceleration of pharmaceutical pollution in many Indian cities, damaging the water, food and health of local populations. 'Good Manufacturing Practices (GMP) require medicines to be of high quality [...] but do not oblige companies to put in place environmental safeguards during production, despite the well-known alarming risks' N. Ticchi, *Salute a tutti i costi* (Torino: Codice edizioni, 2022), 137-138. It is to be hoped that the pharmaceutical reform will have a positive impact on regulation in this area.

<sup>59</sup> [www.ema.europa.eu/en/news/ema-support-establishment-african-medicines-agency](http://www.ema.europa.eu/en/news/ema-support-establishment-african-medicines-agency).

<sup>60</sup> The requirement to submit the result of an environmental risk assessment of a medicinal product at the same time as the marketing authorization application was only introduced after the publication of the Environmental Risk Assessment (ERA) guidelines issued by the EMA in 2006 and last revised in 2018.

<sup>61</sup> Particular attention is also paid to those medicinal products with an antimicrobial mode of action. In this case, the environmental risk assessment also includes an evaluation of the risk of selection of antimicrobial resistance in the environment due to the manufacture, use and disposal of such a medicine.

<sup>62</sup> This is not the place to go over the pieces of the rules governing the centralised authorization procedure. On this point, see Chapter II 'General Provisions and Rules on

193 and 47, para 1, letter d) COM(2023) 192 provide, in fact, for the rejection of the ERA if ‘the environmental risk assessment is incomplete or insufficiently documented by the applicant or the risks identified in the ERA have not been sufficiently addressed by the applicant’. Similarly, Art 195 COM(2023) 192 provides that ‘The competent authorities of the Member States or, in the case of a centralised marketing authorization, the Commission may suspend, revoke or vary an authorization [...] where the authorization holder [...] has identified a serious risk to the environment or public health and has not sufficiently addressed that risk’.

To further strengthen environmental interests, in the phase following the granting of authorization, an obligation is imposed on the beneficiary to periodically monitor the impact of the authorized product, in order to assess the environmental risks also in consideration of the scientific and technological evolution/innovation that contributes significantly to the realisation of the principle of sustainability.<sup>63</sup> Arts 20, para 1, letter c)<sup>64</sup> and 24, para 1, letter f) COM(2023) 193, concerning the suspension of the placing on the market following the notification by the marketing authorization holder of a serious environmental risk, and Art 87 COM(2023) 192, point in this direction. This provision stipulates that the competent authority of the Member State may impose an obligation on the marketing authorization holder to conduct a post-authorization environmental risk assessment study, collect monitoring data, or provide information on use if there are concerns about risks to the environment or public health, including antimicrobial resistance, from an authorized medicinal product or a related active substance.

## **VII. Pharmaceutical Consumer Information as a Tool to Address the Ecological Challenge**

Applications’ and, in particular, the Section headed ‘Application for Centralised Marketing Authorisation’ COM(2023) 192.

<sup>63</sup> On this point, see Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, ‘The European Green Deal’ COM(2019) 640.

<sup>64</sup> The provision stipulates that following authorization, the holder of the authorization must ‘further examine the risks to the environment or public health arising from the release of the medicinal product into the environment if new concerns arise in relation to the authorised medicinal product or other medicinal products containing the same substance’.

The ecological imprinting of the pharmaceutical business is further reinforced by the legislative aim to empower consumers, by strengthening, first and foremost, their right to information. As will be analyzed, consumer participation in decision-making processes and access to information represent tools for the protection of a range of interests, including environmental protection. There is no doubt that information, especially environmental information, is indispensable for ensuring comprehensive knowledge of the multifaceted issues related to this strategic sector and, at the same time, for promoting widespread social oversight. In this perspective, it is argued that information holds significant social and legal value, warranting robust protection.<sup>65</sup> This is the direction taken by Art 101 of the proposal for a regulation, which provides for the establishment by the EMA, in cooperation with the Member States and the Commission, of a database (EudraVigilance) containing information on medicinal products authorized in the Union and establishes an appropriate level of access to the consumer public. In support of this approach, reference is made to Art 104, para 1 COM(2023) 193, which prescribes the creation of a European medicines web-portal to facilitate ‘the dissemination of information on medicinal products authorized or to be authorized in the Union’, and of a register of studies for environmental risk assessment (Art 104, para 3). These are instruments that allow for the sharing of important information, thereby ensuring community participation. Properly informing pharmaceutical consumers is undoubtedly a fundamental tool for meeting the ecological challenge. Obviously, it will be necessary for the consumer to be able to consciously navigate the so-called information ecosystem, not by passively absorbing pre-packaged content but by critically engaging with that information. More precisely, consumers must become aware of being an active configurator of *societas*. Confirmation of the importance of consumer information and education is expressed not only by the European legislator (Art 169 TFEU) but also by the national legislator that, in Art 1, para 2, letters c and d of the consumer code identifies ‘adequate information’ and education as fundamental rights of the consumer to be promoted and protected, enabling consumers to navigate the market critically and achieve, in the best way possible, their well-being. Information can be

<sup>65</sup> ‘Informing and being informed represent a structural necessity of the entire system’, P. Perlingieri, ‘L’informazione come bene giuridico’, in Id, *Il diritto dei contratti fra persona e mercato* (Napoli: Edizioni Scientifiche Italiane, 2003), 336.

configured as a good that contributes to the formation of personality.<sup>66</sup> It is up to the jurist to ensure that the data economy develops in an ethically appropriate and free manner. This confirms that it is not possible to ‘separate scientific-technological investigation from human and social investigation’.<sup>67</sup>

The reform of the pharmaceutical sector, moreover, emphasizes a participatory logic of consumers, recognizing them as bearers of the interest in the proper use of medicinal products for human use. Art 146 paras 1 and 8 of the proposed Regulation (COM(2023) 193) empowers the Scientific Committees, ‘responsible for formulating the Agency’s scientific opinions or recommendations, [...] to organize [...] public hearings [...] on general subjects, at an advisory level [...]. To this end, the Agency shall establish working groups of consumer organisations’.

An informed and aware consumer undeniably has the power to exercise external control as the holder of a general interest in ensuring that pharmaceutical activities align with the objectives of sustainable development.

In short, if ‘the environment is the system that sustains our lives and is everyone’s heritage, [t]he preservation, protection and improvement of *its* quality are common values’.<sup>68</sup> Accordingly, the right to access information and sit at the regulator’s table becomes fundamental to protecting the interest of every person to live in an environment that ensures their well-being.

### VIII. Concluding Remarks

The analysis conducted confirms that the protection of individuals and respect for the *habitat* must be considered as a unified value. This constitutes the foundation of the current constitutional legality, guiding both the legislator and the interpreter to promote in the performance of their activities a new

<sup>66</sup> P. Perlingieri, *Il diritto civile nella legalità costituzionale. Situazioni soggettive* (Napoli: Edizioni Scientifiche Italiane, 2020), III, 134. Appropriate, intelligible, and intelligent information becomes a fundamental tool of democracy. In this way, the Italian Constitutional Court also expresses itself, Corte costituzionale 17 April 1969 no 84.

<sup>67</sup> A. Alpini, ‘La trasformazione digitale nella formazione del civilista’ *Tecnologie e Diritto*, 1, 11 (2021).

<sup>68</sup> The words in inverted commas are used in the European Union Commission’s Notice on Access to Justice in Environmental Matters of 18 August 2017 (C/275-01). On the point, see A. Krezel, ‘Aarhus Regulation Administrative (self-) Review Mechanism: The Inevitable Failure to Contribute to Access to Justice in the EU?’ 32 *European Energy and Environmental Law Review*, 136-144 (2023).



legal-economic order that is indispensable for 'human soteriology'. The environmental interest, as the foundation of the continued enjoyment of fundamental rights in the future, shapes the entire legal experience. It is in this context that the review of pharmaceutical activity arises, which, in accordance with the Italian-European axiology, must be realized in accordance with the principle of sustainability.