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Working Paper 2023/2

The risks of the interaction between soft and hard law without adequate systems of control.

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Introduction

Over the past decades, soft law has succeeded in occupying its place amidst the sources of EU law.[2] Given its capacity to evolve in, substitute, and complement secondary law, it constitutes an important element in the debate on the interaction between EU law sources. The use of soft law accommodates the necessity of a flexible, fast, and specialised regulatory practice, which represents an advantage for both exceptional scenarios, such as the 2008 economic crisis and the Covid-19 health crisis, and normal circumstances, when the European Commission and EU specialised Agencies increasingly rely on soft law to enhance or smoothen the application and interpretation of other EU legal norms. In both cases, soft law represents an inevitable supply mechanism of EU secondary legislation.

Soft law generates a governance model beneficial for an effective and correct implementation of EU secondary legislation. However, the advantages of this practice come at the expenses of principles and guarantees of EU law. In that sense, Senden claims that in the soft law-making process the principles of openness, transparency, consultation, and participation, which generally serve as tools of empowerment and involvement of citizens in the EU decision-making process, and the relevant procedural rules and mechanisms which make these principles operative are sacrificed in order to guarantee the effectiveness of EU law.[3] In more details, as regards soft law-making in the field of climate change, literature emphasises how soft law selectively and inconsistently adheres only to some legitimacy principles, mainly as a consequence of the lack of an overarching framework laying down the procedures and institutional practices to be followed.[4] In addition, empirical research shows how during the Covid-19 health crisis, the Commission's soft law insufficiently respected the Union democratic credentials, especially in terms of European Parliament's involvement and stakeholders' consultation.[5]

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[2] Within the scope of this paper, the term "soft law" denotes non-binding instruments like recommendations, opinions, communications, guidelines, and other quasi-legal tools that lack formal binding nature and are not subject to judicial enforcement. For more details, see Linda Senden, *Soft Law in European Community Law* (Hart Publishing 2004) 55-56.

[3] Linda Senden 'Soft Post-Legislative Rulemaking: A Time for More Stringent Control' (2013) 19 European Law Journal, 57, 67-70.

[4] Danai Petropoulou Ionescu and Mariolina Eliantonio 'Soft Law Behind the Scenes: Transparency, Participation and the European Union's Soft Law Making Process in the Field of Climate Change' (2023) 14 European Journal of Risk Regulation 292.

[5] Mariolina Eliantonio and Oana Ştefan 'The Elusive Legitimacy of EU Soft Law: An Analysis of Consultation and Participation in the Process of Adopting COVID-19 Soft Law in the EU' (2021) 12 European Journal of Risk Regulation 159; Oana Ştefan 'COVID-19 Soft Law: Voluminous, Effective, Legitimate? A Research Agenda' (2020) 5 European Papers 663.

More generally, this soft-oriented model of governance is criticised since it marks a departure from the 'Community Method'.[6] In fact, at odds with the basic division of powers elaborated by the EU Treaties, where the European Commission, the European Parliament, and the Council must respectively exercise their powers with due regard to the powers of other institutions,[7] the Commission's soft law is generally the result of fast and flexible adoption procedures that escape the interinstitutional and comitology control. Additionally, the Commission's competence to use soft law instruments operates in a grey area, especially in the light of the absence of formal recognition of soft law among the EU law sources in the Treaties.[8]

Under these circumstances, the utilisation of soft law underscores an ambiguity. Although being frequently employed, soft law is commonly criticised for not respecting important democratic principles and procedures and entailing a disruption of the EU institutional balance.[9] To solve this ambiguity, this article suggests improving the judicial review of soft law.

To develop this argument, the first part of this article will start by exploring how soft law has been used in the EU governance design, becoming an inevitable supply mechanism of other sources of EU law. This analysis is conducted within the sectors of EU pharmaceutical regulation and State aid. These two policy fields have a high predominance of soft law over hard law.[10] More precisely, these pre-selected sectors reflect, according to the scope of definition of soft law used for the collection of data, a predominance or at least relevance of soft law over hard law.[11] The second part of the article will discuss the justiciability of soft law. Drawing inspiration from the few existing works on the topic,[12] the specific issue on which this part engages is that although the Court of Justice of the European Union

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[6] For a definition of 'Community Method', see Merijn Chamon, 'Institutional Balance and Community Method in the Implementation of EU Legislation Following the Lisbon Treaty' (2016) 53 Common Market Law Review 1501, 1504; Renaud Dehousse, 'Has the European Union moved towards soft governance?', (2015) 14 *Comparative European Politics* 20.

[7] Article 13(2) TFEU; Case C-133/06 *Parliament v Council* [2008] ECR I-3189, para 57.

[8] Linda Senden 'Soft law and its implications for institutional balance in the EC' (2005) Utrecht Law Review 79, 86; and European Parliament resolution of 4 September 2007 on institutional and legal implications of the use of "soft law" instruments (2007/2028(INI)).

[9] For a definition of institutional balance, see Case C-9-56, *Meroni & Co., Industrie Metallurgiche, SpA v High Authority of the European Coal and Steel Community* [1958] ECLI:EU:C:1958:7. For further discussions on the principle of institutional balance, see Amaryllis Verhoeven and Koen Lenaerts, 'Institutional Balance as a Guarantee for Democracy in EU Governance' in (eds) Christian Joerges and Renaud Dehousse, Good Governance in Europe's Integrated Market (OUP 2002), 47. The authors describe institutional balance as political principle that must guide the choice of the legal basis and the competent institution. In addition, Merijn Chamon, 'The Institutional Balance, an Ill-Fated Principle of EU Law?', (2015) 21 European Public Law 371. The author distinguishes institutional balance from the principle of separation of powers.

[10] Bartolomeo Cappellina et al, 'Ever more soft law? A dataset to compare binding and non-binding EU law across policy areas and over time (2004–2019)' (2022) 23 *European Union Politics* 741. The EfSoLaw dataset maps soft law across different policy sectors, namely sustainable agriculture, food safety, Common Foreign and Security Policy, and police/judicial cooperation, financial regulation, pharmaceutical regulation, and State aid.

[11] Ibid, 752. The authors use an inclusive and a restrictive definition of soft law and collect two separate samples: sample 1 (inclusive) includes instruments that do not have legally binding force but might produce certain indirect legal effects, or they are aimed at and may produce practical effects. Sample 2 (restrictive) refers to soft law instruments that reflect some degree of formalisation and legal and practical effects.

[12] Mariolina Eliantonio and Oana Ştefan, 'Soft Law Before the European Courts: Discovering a 'common pattern'?' (2018) 37 Yearbook of European Law 457; Mariolina Eliantonio, 'Soft Law in Environmental Matters and the Role of the European Courts: Too Much or Too Little of It?' (2018) 37 Yearbook of European Law 496; Joanne Scott 'In Legal Limbo: Post-legislative Guidance as a Challenge for European Administrative Law' (2011) 48 Common Market Law Review 329; Oana Ştefan, 'European Union Soft Law: New Developments Concerning the Divide Between Legally Binding Force and Legal Effects' (2012) 75 Modern Law Review 879; Oana Ştefan, *Soft Law in Court: competition Law, State Aid and the Court of Justice of the European Union* (Wolters Kluwer 2013).

(hereafter referred as 'Court of Justice', 'Court' or 'CJEU') invested itself with the power to interpret non-binding EU instruments in some specific circumstances, limitations persist to this activity.[13] Within this framework, this article concludes submitting that a consistent approach would be that of indirectly questioning the validity of soft law through references for a preliminary ruling, instead of a direct review through actions of annulment.

Part I – Soft law as an inevitable supply mechanism.

Soft law helps addressing the potential lack of clarity, comprehensiveness, and effectiveness of other sources of EU law, eventually contributing to the correct functioning of the EU legal system. In doing so, however, soft law is irrespective of legitimacy credentials and of the evident disruption of institutional balance that it produces. In other words, EU is progressively adopting an alternative system of governance that varies in terms of how the interinstitutional relationships are shaped and so, in terms of legitimacy. Against this background, this softer governance model, with the specific characteristics that it entails, has made itself indispensable. Soft law has, in fact, become an inevitable supply mechanism of hard law.

This part explores further this claim through a textual analysis of how secondary legislation and soft law instruments interact in the field of EU pharmaceutical regulation and State aid. In this context, the amount of soft and hard law within these two policy areas would make rather complex to conduct a textual analysis in its integrity. Therefore, the analysis below will be limited to some central instruments in these two areas (see Table 1).[14]

Table 1: Secondary sources and soft law.

Sector.	***Secondary sources.***	***Soft law.***
Pharmaceuticals	Regulation 726/2004	Commission Guideline — Guidance on posting and publication of result-related information on clinical trials in relation to the implementation of Article 57(2) of Regulation (EC) No 726/2004 and Article 41(2) of Regulation (EC) No 1901/2006.[15]
	Directive 2001/83	Guidelines on principles of Good Distribution Practice of active substances for medicinal products for human use.[16]
		Guidelines on the formalised risk assessment for ascertaining the appropriate good

[13] Case C-322/88 *Salvatore Grimaldi v Fonds des maladies professionnelles* [1988] ECLI:EU:C:1989:646.

[14] To identify the specific soft law instruments, which are linked to the pre-identified secondary sources, further research on the EUR-Lex engine was carried out by using the filter 'select all documents based on this document'. The results were then screened by type of act and author. This allowed to access to a limited number of secondary legislation and soft law documents (see Table 1), which are, under different degrees, interconnected. Within this context, taking into account that soft law is produced by a patchwork of different bodies, this paper intends to focus on soft law produced by EU institutions and the shift of institutional balance among them.

[15] Commission Guideline — Guidance on posting and publication of result-related information on clinical trials in relation to the implementation of Article 57(2) of Regulation (EC) No 726/2004 and Article 41(2) of Regulation (EC) No 1901/2006 [2012] OJ C 302/7.

[16] Guidelines of 19 March 2015 on principles of Good Distribution Practice of active substances for medicinal products for human use [2015] OJ C 95/1.

		manufacturing practice for excipients of medicinal products for human use.[17]
		Guidelines on Good Distribution Practice of Medicinal Products for Human Use.[18]
State aid	Regulation 2015/1589	Commission Notice on the recovery of unlawful and incompatible State aid.[19]

Case study.

Pharmaceuticals.

The EU legal framework on medicinal products is a rather elaborated patchwork of both legislative and soft law instruments. In that context, Directive 2001/83 and Regulation 726/2004 constitute the general legislation regulating medicinal products. More precisely, Directive 2001/83 incorporates the principles and rules regulating Member States' marketing authorisation, manufacture and importation, distribution, advertising, and vigilance of medicines, and Regulation 726/2004 lays down the procedures for the Union authorisation and supervision of medicinal products for both human and veterinary use as well as establishes the European Medicine Agency (EMA). Besides, other pieces of EU legislation have been developed to address specific types of medicinal products,[20] to guarantee medicinal products' quality and safety,[21] and the good functioning of the internal market.[22] At the same time, in light of the limited EU competence on health under Art. 168 TFEU, the regulation of pharmaceutical remains incisively regulated by each Member State. Additionally, the employment of soft law instruments has allowed the Commission to extensively regulate this field, circumventing the limited EU competence and the potential political obstructionism of the Member States. Despite so, the Commission's soft regulation has operated in the boundaries of secondary legislation, as the analysis below will show.

As regards the assessment of the interaction between soft and hard law instruments (see Table 1), it emerges that the guidelines figuring in Table 1 are strictly linked to Directive 2001/83 and Regulation 726/2004. The Guidelines on Good Distribution Practice of Medicinal Products for Human Use (Guidelines on GDP) are issued on the basis of Articles 84 and 85b (3) of Directive 2001/83. By laying down standards to assist wholesale distributors in conducting their activities, these guidelines aim to contribute to the maintenance of the quality and the integrity of medicinal products. For this reason, the compliance to these guidelines is stressed by Article 80(g) of Directive 2001/83, which requires distributors to comply with the principles of and guidelines on GDP.
Similarly, the Guidelines on principles of Good Distribution Practice of active substances (Guidelines on GDB of active substances) and the Guidelines on the formalised risk assessment for ascertaining the

[17] Guidelines of 19 March 2015 on the formalised risk assessment for ascertaining the appropriate good manufacturing practice for excipients of medicinal products for human use [2015] OJ C 95/10.
[18] Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use [2013] OJ C 343/1.
[19] Communication from the Commission — Commission Notice on the recovery of unlawful and incompatible State aid C/2019/5396 [2019] OJ C 247/1.
[20] For instance, Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products, [2000] *OJ L 18/1*; Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004, [2006] OJ L 378/1.
[21] For instance, Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC [2014] OJ L 158/1.
[22] For instance, Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products [2009] OJ L 152.

appropriate good manufacturing for excipients of medicinal products for human use are issued on the basis of Article 47 (4) and (5) of Directive 2001/83. In this context, the holders of distribution authorisation have to comply with the GDP for active substances, as required by Articles 46(f), 46*b* and 80(g), under the supervision of national competent authorities, which can conduct inspections on distributors on the compliance with the GDP.
An equivalent discourse applies to the Commission Guideline containing guidance on posting and publication of result-related information on clinical trials. This instrument implements Article 57(2) third sub-paragraph of Regulation 726/2004, which requires the Commission, in consultation with the Member States, to issue these guidelines. The Commission Guidance lays down procedural rules for posting result-related information on clinical trials and thus, contributes to the achieving the regulation's policy aim of making the results of clinical trials available.

Within the framework, soft law instruments are strongly linked to secondary legislation.

State aid.

The 2019 Recovery Notice provides for a detailed guidance for Member States to effectively implement European Commission's recovery decisions. This Notice replaces the 2007 Recovery Notice, which has proved to be inadequate in supporting Member States in the implementation of State aid recovery decisions.[23] In light of the 2012 State Aid Modernisation ('SAM'),[24] the 2019 Recovery Notice aims to increase transparency as regards the Commission's practice on recovery of State aids and most importantly, explains how the cooperation between the Commission and the Member States in this field works. It aims to provide for a more solid procedural framework for the enforcement of recovery decisions and contribute to the correct functioning of Regulation 2015/1589 ('Procedural Regulation').[25]
It is important to stress that the Recovery Notice does not introduce a new and/or alternative interpretation of existing secondary rules. Conversely, this Notice reproduces the state of the art of the current legislation on State aid and implements the case law of the Court of Justice about recovery policy.[26] In 1973, the Court of Justice formally acknowledged the competence of the European Commission to order the recovery of unlawful and incompatible aids.[27] Following this case law, the recovery of State aids was thus firstly established in practice, alongside a Communication recalling the Member States' duty to notify any plans to grant or alter aids,[28] which was expressed by the EU Treaty. Only, in 1999, this practice was codified by Regulation 659/1999.[29]

Under these circumstances, soft law comes to rescue the feeble capacity of EU secondary legislation to provide guidance as regards its own implementation. This is particularly relevant in a system based on indirect enforcement of law. Indeed, the functioning of the recovery procedure strongly depends on the intention and capacity of the Member States to notify, correctly and timely, the European Commission of any proposed aid measure in favour of undertakings. Moreover, while, initially, the

[23] Jan Blockx, 'New EU State aid Recovery Notice strengthens Commission's hand' (Kluwer Competition Law Blog, 27 July 2019) <https://competitionlawblog.kluwercompetitionlaw.com/2019/07/27/new-eu-state-aid-recovery-notice-strengthens-commissions-hand/>
[24] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions EU State Aid Modernisation (SAM) - COM/2012/0209
[25] Council Regulation 2015/1589 (n 13), Article 16.
[26] Simone Donzelli 'The Commission's New Recovery Notice: A Handbook for the Recovery of Unlawful and Incompatible Aid' (2019) 18 European State Aid Law Quarterly 528.
[27] Case C-70/72 *Commission v Germany* ECLI:EU:C:1973:87, para 13.
[28] Commission Communication [1983] OJ C 318, 3.
[29] Council Regulation 1999/659/EC of 22 March 1999 laying down detailed rules for the application of Article 93 of the EC Treaty [1999] OJ L 83/1.

enforcement of State aid law was centralised at EU level – in the sense that the Commission was vertically empowered to enforce competition and State aid rules – the implementation of competition law drastically changed with Regulation 1/2003. The delegation of implementing powers as regards competition rules and State aid to national competition authorities, in parallel to the European Commission, demands for more soft law instruments to guide these authorities in the exercise of their enforcement tasks.[30]

Outcomes.

The above analysis presents two distinct scenarios of how the interaction between soft law and secondary legislation takes place in practice. Pharmaceutical legislation includes explicit provisions enabling the European Commission to issue guidelines and recommendations, whereas Regulation 2015/1589 on State aid does not include similar requirements. However, in both circumstances, soft law provides an added value to the existing system of powers and norms. The regulatory mix of hard and soft law serves to explicitly complement the content of secondary legislation, as in the case of pharmaceutical, or to better define, for purposes of clarity and implementation, the content and scope of existing rules and principles, as emerged from the case study on State aid. These elements suggest that soft law represents an inevitable supply mechanism of other sources of EU law, in the sense that it aims to provide something that hard law did not do (supply), and thereby, making its presence indispensable for the enforcement of EU law (inevitable).

At this stage, the question is not anymore about the necessity or desirability of soft law instruments, but rather which mechanisms of control could be best placed to not leave this system of governance unchecked. The introduction of a judicial mechanism for oversight could enhance the legitimacy of this new governance model determined by the use of regulatory instruments extraneous to the EU Treaty framework. The next part will further develop this argument.

Part II – Is soft law also 'inevitable' in the Court of Justice's case law?

In a legal system composed of multiple EU sources, it is not surprising that different procedures apply to different sources of EU law. However, soft law-making has been radical in cutting the ties with standard procedures, eventually lacking democratic control and sporadically applying principles of good governance, such as openness and transparency.[31] For instance, in the context of pharmaceutical, it was noticed that Article 47(4) of Directive 2001/83 formally empowers the European Commission to issue guidelines on GDP on active substances. Despite this delegation to act derives directly from an act of secondary legislation, which was issued according to a legislative procedure in which the European Parliament and Council were equally involved, it does not add specific procedural conditions for issuing such guidelines.[32]

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[30] Oana Ştefan et al. 'EU Competition and State Aid Soft Law in the Member States: Finland, France, Germany, Italy, the Netherlands, Slovenia and the UK' (2020) King's College London Law School Research Paper Forthcoming

[31] Anton van den Brink and Linda Senden 'Checks and Balances of Soft EU Rule-Making' (Policy Department C: Citizens' Rights and Constitutional Affairs, 19 April 2012) <https://ssrn.com/abstract=2042480 or http://dx.doi.org/10.2139/ssrn.2042480>; Danai Petropoulou Ionescu and Mariolina Eliantonio 'Democratic Legitimacy and Soft Law in the EU Legal Order: A Theoretical Perspective' (2021) 17 Journal of Contemporary European Research 43.

[32] Article 47 (4) of Directive 2001/83 empowers the European Commission to adopt guidelines on principles on GDP for active substances, without imposing any procedural condition. Article 47 (3) of Directive 2001/83 requires the Commission to adopt principles and guidelines of good manufacturing practice for active substances by means of delegated acts and thus, to comply for their adoption with the procedures and conditions determined by Articles 121a, 121b and 121c of that directive.

To address the many procedural shortcomings related to soft law making includes, literature suggests to strengthening the role of impact assessment and comitology control, and a major involvement of the European Parliament.[33] Against the background, this research does not aim to further focus on the gaps in the procedural checks in the EU Treaty system, which are to some extent related to a paralysis of a Treaty reform. Conversely, it stresses the possibility to apply existing mechanisms of judicial control to soft law instruments in order to assess the respect of the constitutional guarantees in terms of allocation of powers as determined by the EU Treaties. In this context, it goes without saying that the Court of Justice might play a crucial role to counterbalance any unfair disturbance to the institutional balance while persevering the correct functioning of the EU legal order. Advocate General Bobek has indeed claimed that the review of legality of soft law by the CJEU upholds the principle of institutional balance.[34] Likewise, in doctrine, among the others, Senden claims that the CJEU' judicial review could indeed represent a tool to counterbalance the feeble procedural guarantees of soft post-legislative rulemaking.[35] As well, Scott envisages in the post-legislative guidance of European courts' judicial review a way to counterbalance the many procedural shortcomings of soft law-making.[36]

Nevertheless, many obstacles remain as regards the CJEU's judicial review of the legality of soft law. Despite some claims to ensure the judicial review of soft law via action for annulment,[37] the CJEU has repeatedly excluded this solution,[38] recalling that an EU act that is not legally binding cannot be reviewed under Article 263 TFEU. However, in a system of remedies that claims to be complete, the limited access under Article 263 TFEU might be complemented by the procedure established by Article 267 TFEU, which gives to the Court the jurisdiction to give a preliminary ruling on the validity and interpretation of all acts of the EU institutions without exception. In this view, a valid and already explored solution could be that of the indirect review of the validity of soft law through references for a preliminary ruling. This approach allows to countercheck any alleged interference with the institutional balance, through the review of the legality of soft law acts, while contributing to the uniform application of EU, as well as to guarantee the correct function of the EU legal system, filling a gap in the EU system of remedies. Indeed, when the institutional balance is likely to be affected, the overall legitimacy of the EU legal system is affected.[39]

The Court of Justice has already put into practice this approach. In *FBF,*[40] the French Council of State referred three questions to the CJEU in relation to a national dispute, where the French Banking Federation's (FBF) challenged an act of the French Prudential Control and Resolution Authority, which complies with the European Banking Authority's (EBA) guidelines on product oversight and governance arrangement for retail banking products. In this context, the applicant argued that EBA lacked the competence to adopt such guidelines. This represented an opportunity for the Court of Justice to make clarity as regards the issue of judicial review of EU soft law.[41] Indeed, the preliminary questions raised

[33] van den Brink and Senden (n 31) 84; Senden (n 3) 67-70.
[34] Case C-16/16 P *Kingdom of Belgium v European Commission* ECLI:EU:C:2017:959, Opinion of Advocate General Bobek, para 94.
[35] Senden (n 3) 73.
[36] Scott (n 12).
[37] Giulia Gentile 'Ensuring Effective Judicial Review of EU Soft Law via the Action for Annulment before the EU Courts: a Plea for a Liberal-Constitutional Approach' (2020) 16 European Constitutional Law Review 466
[38] Case C-16/16 P *Belgium v Commission* [2018] ECLI:EU:C:2018:79, para 31.
[39] Case C-911/19 *Fédération bancaire française (FBF) v Autorité de contrôle prudentiel et de résolution (ACPR)* [2021] ECLI:EU:C:2021:294, Opinion of Advocate General Bobek, para 86.
[40] Case C-911/19 *Fédération bancaire française (FBF) v Autorité de contrôle prudentiel et de résolution (ACPR)* [2021] ECLI:EU:C:2021:599.
[41] Case C-501/18 *BT v Balgarska Narodna Banka* [2020] ECLI:EU:C:2020:729, Opinion of Advocate General Campos Sánchez-Bordona, footnote 64; Merijn Chamon and Nathan de Arriba-Sellier 'FBF: On the Justiciability of Soft Law and Broadening the Discretion of EU Agencies' (2022) 18 European Constitutional Law Review 286;

concerns over the possibility to annul the contested guidelines under Article 263 TFEU or to challenge their validity by means of reference for a preliminary ruling under Article 267 TFEU, and whether EBA has the power to issue such guidelines.[42] In this context, the Court excluded that the guidelines could be the subject to an action for annulment, while it declares to have 'jurisdiction to give a preliminary ruling on the validity of a recommendation of the EBA which does not have binding legal effects', explicitly recalling the previous *Balgarska Narodna Banka* (BNB) case.[43] Indeed, for the first time, in *BNB*, the Court answered on the question of validity of non-binding acts, declaring the EBA's contested recommendations invalid.

However, this approach raises some concerns. So far, in both circumstances the CJEU was called to review the legality of soft law acts of the EBA. Moreover, the CJEU did not present supportive arguments as regards this approach, beside a general reference to Article 267 TFEU.[44] In that sense, it is rather premature to conclude that the Court of Justice will generally assess the validity of soft law acts within the preliminary reference procedure to potentially declare any type of soft law act invalid.

Moreover, the indirect review of the legality of soft law through preliminary references might further emphasise the gateway role of national courts, which will become unilaterally responsible to decide to refer such issues of validity to the CJEU.[45] At the same time, privileged applicants under Article 263 TFEU, namely EU Member States, the European Parliament, and the Council, would be in practice deprived of this 'title'. In that sense, the declared intention to use the indirect review of the legality of soft law by means of preliminary ruling procedures to rescale the lost institutional balance will also partly vanish. In other words, the European Parliament will not be able to ask for the review of legality of acts of the European Commission.
An additional practical challenge is the lack of justiciability of soft law among national courts.[46] Since *Grimaldi*, where the Court of Justice considered that a recommendation, despite being formally deprived of binding force, was not deprived of legal effects and for this reason, national courts should take it into account when deciding disputes, research shows that it remains a common trend among national courts of the Member States to declare inadmissible actions brought against soft law instruments.[47] Despite some jurisdictions have progressively opened up their system of judicial review to include acts that are not strictly speaking binding,[48] in practice, these instruments are simply quoted or referred to reinforce a certain argument.[49]

Keeping this in mind, the complexity of the judicial review of soft law goes back to the uncertainty that surrounds the nature of soft law. The wide array of instruments of soft law, such as guidelines, communications, notices, recommendations, opinions, does not fit within the binary distinction between binding and non-binding legal effects. Despite, in principle, soft law instruments lack formal

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Heikki Marjosola, Marloes van Rijsbergen, and Miroslava Scholten 'How to exhort and to persuade with(out legal) force: Challenging soft law after FBF' (2022) 59 Common Market Law Review 1523.

[42] Case C-911/19 *FBF* (n 44) para 34.

[43] Ibid, para 56.

[44] Pavlína Hubková 'Judicial review of EU soft law: a revolutionary step which has not fully happened (Case note on BT v. Balgarska Narodna Banka, C-501/18)' (2021) 55 Revista General de Derecho Europeo 174.

[45] Mira Scholten 'How to exhort and to persuade with(out legal) force: Challenging soft law after FBF'(2022) Common market law review 59 1523.

[46] Mariolina Eliantonio 'Judicial review of soft law before the European and the national courts - A wind of change blowing from the member states?' in (eds.) Mariolina Eliantonio, Emilia Korkea-aho, and Oana Stefan *EU soft law in the member states: Theoretical findings and empirical evidence* (Hart Publishing. EU law in the Member States, 2021) 300.

[47] CJEU, *Research Note on the Admissibility of court actions against 'soft' law measures* (2017)

[48] Case C-16/16 P, Opinion of Advocate General Bobek, (n 34), 84-85.

[49] Oana Stefan, 'European Competition Soft Law in European Courts: A Matter of Hard Principles?' (2008) 14 European Law Journal 753.

legally binding force, practice suggests that soft law has progressively become *de facto* binding, producing legal effects such as expressing general principles of EU law, concretising the duty of cooperation between EU institutions and Member States, interpreting hard law provisions for the purpose of their implementation, and have an important impact on the rights and obligations of individuals.[50] For instance, the case study conducted above has further highlighted that soft law instruments are meant to produce some legal effects and might, in some circumstances, be binding. This is particularly – but not exclusively – the case of post-legislative soft law instruments that are adopted on the basis of a piece of secondary legislation, such as the Guidelines on principles of Good Distribution Practice of active substances for medicinal products, to which, according to Art. 80 of Directive 2001/83, holders of the distribution authorisation must comply.

Against this background, problematic remains the case law of the Court of Justice, which, only exceptionally, contains a detailed examination of soft law and discusses its legal effects. Remarkably, the *Polska Telefonia Cyfrowa* judgment, to some extent, clarifies the legal effects of soft law instruments, distinguishing between their legally binding force and their legal or practical effects.[51] The Court recalls that the European Commission guidelines under scrutiny 'do not lay down any obligation capable of being imposed, directly or indirectly, on individual',[52] however, national regulatory authorities are not prevented from referring to them. Overall, however, the approach adopted by the Court confirms the reluctance to accept the practical effects of soft law in terms of rights and obligations that can produce on individuals, while acknowledging their effects in some limited circumstances. The consequence of this mismatch is that the soft law remains unchecked by the Court of Justice while continuing to produce effects in practice.[53]

Conclusions

This article highlights the relevance of soft law for the enforcement of EU secondary legislation. To that end, it conducts an analysis of the interaction between soft and hard law in the field of pharmaceutical and State aid. In this context, soft law emerges, under different extents, a necessary supply mechanism of other sources of EU law. At the same time, soft law is criticised for lacking legitimacy and disrupting the principle of institutional balance. These allegations are supported by the fact that soft law-making remains unchecked. Against these allegations, this paper suggests an increased judicial control by the Court of Justice, exploring the possibility of indirectly assessing the legality of soft law by means of references for preliminary ruling.

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[50] Francis Snyder, *Interinstitutional agreements : forms and constitutional limitations* (European university institute, 1995) 463.

[51] Case C-410/09 *Polska Telefonia Cyfrowa sp. z o.o. v Prezes Urzędu Komunikacji Elektronicznej* [2011] ECR I-03853.

[52] Ibid, para 34.

[53] Christine Chinkin 'The Challenge of Soft Law: Development and Change in International Law' (1989) 38 The International and Comparative Law Quarterly 850, 862–865.