Common Market Law Review **59**: 1333–1370, 2022.

EU COVID-19 PURCHASE AND EXPORT MECHANISM: A FRAMEWORK FOR EU OPERATIONAL AUTONOMY

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Abstract

The burgeoning debate on EU strategic autonomy calls for an appraisal of the role of law in the pursuit of the EU's strategic objectives. This article examines EU executive measures regarding procurement and free movement regulation of critical resources and vaccines in the wake of the COVID-19 outbreak. It introduces the notion of EU operational autonomy to account for the mixed operative framework governing the joint actions of the Union and its Member States. The article argues that this framework heralds new patterns of executive centralization whereby political motives increasingly inform legal structures. It identifies the internal and external facets of EU operational autonomy, and highlights the composite dynamics emerging from neighbouring country association to EU operational autonomy. The study of these dynamics also offers insights into the complex balance between the EU's regional and multilateral commitments.

1. Introduction

Autonomy has entered the policy priorities of the Union in the context of a growing demand for a pronounced political role for the Commission and a more assertive geopolitical standing of the Union.[1] With regard to the COVID-19 crisis, the European Commissioner holding the Internal Market portfolio vividly maintained that the pandemic "enabled us to understand that the corollary to our freedom is our autonomy".[2] Against this backdrop, the

* Postdoctoral Fellow, University of Oslo. This research has been carried out with the generous support of the EUI's Max Weber Programme.

1. See Speech by President-Elect von der Leyen in the EP, Strasbourg (27 Nov. 2019), referring to a "geopolitical Commission"; see also Kassim and Laffan, "The Juncker presidency: The 'political Commission' in practice", 57 JCMS (2019), 49; Gstöhl, "The geopolitical Commission: Learning the 'language of power'?", College of Europe Policy Brief (Feb. 2020).

2. Breton, "Our (European) Union makes us stronger", *European Commission, Blog pos*t (27 Aug. 2021), </ec.europa.eu/commission/commissioners/2019-2024/breton/blog_en> (all websites last visited 18 July 2022).

present article introduces the notion of EU operational autonomy to unravel the interface between legal frameworks and political choices in the pursuit of the EU's strategic objectives. The EU COVID-19 vaccines purchase and export mechanism is used as a case study for disclosing how legal structures and political rationales are intertwined. The mechanism is paradigmatic of the legal arrangements and mechanics sustaining the EU operational autonomy framework, consisting of executive centralization and joint (mixed) involvement of the EU and its Member States.

The operational perspective on autonomy, which focuses on the EU executive powers and on the law in practice aspects, contributes to bridging legal and international relations studies on EU strategic autonomy.[3] EU strategic autonomy amounts to the EU's capacity to "live by its laws", set and pursue its own objectives, without necessarily entailing "independence, less still unilateralism or autarky".[4] The Commission relates the Union's strategic autonomy to the EU's "capacity and freedom to act".[5] The cognate notion of EU operational autonomy developed in this article captures the features of a legal framework which leverages on the combined economic and political weight of EU Member States and the EU's closest neighbouring partners in the pursuit of European strategic objectives.

After contextualizing the Member States' responses to the COVID-19 crisis in light of EU internal market law (section 2), the article unravels the EU operational autonomy framework in its internal and external components. Internally, EU operational autonomy has emerged in the exercise of the Commission's executive powers leading to the procurement and advance purchase of critical goods and vaccines. This unitary framework governing the joint actions of the EU and its Member States has been predicated on the exercise of the Commission budgetary functions and the overhaul of the Emergency Support Instrument (ESI) Regulation.[6] While premised on internal market logic of optimal allocation of resources, the development of the internal dimension of EU operational autonomy marked a paradigm shift in the exercise of the EU's public powers: it paved the way for a more active intervention of the executive in the economy to pursue the EU's strategic objectives (section 3). Externally, EU operational autonomy has taken the

3. See on this, Editorial Comments, "Keeping Europeanism at bay? Strategic autonomy as a constitutional problem", 59 CML Rev. (2022), 313.

4. Tocci, "European strategic autonomy: What it is, why we need it, how to achieve it", Istituto Affari Internazionali (2021), p. 3, available at <www.iai.it/en/pubblicazioni/european-strategic-autonomy-what-it-why-we-need-it-how-achieve-it>.

5. COM(2021)750 final, Commission Communication, "2021 Strategic Foresight Report, The EU's capacity and freedom to act" (8 Aug. 2021).

6. Council Regulation (EU) 2016/369 on the provision of emergency support within the Union, O.J. 2016, L 70.

form of the exercise of the Commission implementing powers in the domain of the EU trade policy, which resulted in EU-wide export authorization mechanisms. These were aimed at safeguarding the Union's security of supply of critical resources and vaccines. Member States' participation has been significant – not only in the operative application of the measures, but also in the comitology procedures governing the exercise of the Commission trade implementing powers (section 4).

The article brings to the fore the third country association to EU operational autonomy. It identifies the composite dynamics of internal and external EU operational autonomy within the Union's external relations, especially in its neighbourhood. It discusses how these forms of third country association reconfigured the scope of the public interest and strategic objectives in the wider European legal space, beyond the EU. The different echelons of association to EU operational autonomy in the EU neighbourhood are also assessed. A special focus is placed on the most developed forms of association, concerning the countries of the European Economic Area (section 5). Finally, the article evaluates the tension and delicate balance between the EU's regional and international commitments. It assesses the relation of the EU's own purchase and trade mechanism with COVAX and reviews the compatibility of the exemption regime of the export control mechanism with GATT rules (section 6).

In its internal and external facets as well as in its associative dimension, the EU's operational autonomy framework has enabled the Union to manage the procurement and free movement regulation of critical resources and vaccines. It has enhanced the freedom of the Union to act in the pursuit of European strategic objectives. A key quality and priority of that autonomous framework has been unity, both as a legal feature and a policy choice. Unity, in fact, has fostered the effectiveness of the joint actions of the EU and its Member States while nurturing solidarity at a broader European level.

2. The context of the pandemic and free movement of goods

The initial responses of EU Member States to the COVID-19 outbreak were liable to generate fragmentation in European Union law and threaten the political and legal viability of the internal market. Member States' measures consisted in export bans and the requisitioning of critical goods considered necessary to face the pandemic.[7] While in internal market law, restrictions on

7. For France see *Décret n° 2020-190 du 3 mars 2020 relatif aux réquisitions nécessaires dans le cadre de la lutte contre le virus covid-19*, (NOR:SSAZ2006487D), for Germany see

free movement of goods are generally precluded both with respect to imports (Art. 34 TFEU) and exports (Art. 35 TFEU), Article 36 TFEU envisages derogations to these prohibitions. The provision contemplates measures aimed at "the protection of health and life of humans, animals or plants". The proportionality test with respect to the objective pursued is essential for gauging the compatibility of restrictive national measures with EU law,[8] and for ensuring that they do not "constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States".[9]

The protection of public health is hence one of the sensitive national domains where the materialization of borders within the EU internal market is potentially permitted under the conditions set by EU law. In this domain, EU law defers to Member States' discretional choices.[10] As early as *de Peijper*, the Court affirmed that "health and the life of humans rank first among the property or interests protected by Article 36 [TFEU] and it is for the Member States, within the limits imposed by the Treaty, to decide what degree of protection they intend to ensure".[11] Different standards of protection are thus allowed across the internal market in light of the Member States' national policy objectives.[12] In the application of Article 36 TFEU, restrictive discrete national measures must be reconciled with the design and operation of the EU internal market, portrayed as "an area without the internal frontiers' ensuring the free movement of goods, persons, services and capital".[13]

In the development of the EU legal order, possible threats to the unity of the internal market posed by fragmented national measures have been limited through the promotion of a broader understanding of health protection. The

Anordnung von Beschränkungen im Außenwirtschaftsverkehrmit bestimmten Gütern vom 4. März 2020 (BAnz AT 04.03.2020 B1), for Italy see *Decreto Legge n. 18 del 17 marzo 2020 Misure di potenziamento del Servizio sanitario nazionale e di sostegno economico per famiglie, lavoratori e imprese connesse all'emergenza epidemiologica da COVID-19* (20G00034) (GU Serie Generale n.70 del 17-03-2020). See further on this, Glöckle, "Export restrictions under scrutiny – the legal dimensions of export restrictions on personal protective equipment", *EJIL: Talk!* (7 April 2020). For a review of further national protective measures, see Pirker, "Rethinking solidarity in view of the wanting internal and external EU law framework concerning trade measures in the context of the COVID-19 crisis", 5 *European Papers* (2020), 573, at 574.

8. See e.g. Case C-180/96*, United Kingdom* v. *Commission*, EU:C:1998:192, para 93.

9. Art. 36 TFEU.

10. Zglinski, "The rise of deference: The margin of appreciation and decentralized judicial review in free movement law", 55 CML Rev. (2018), 1341, at 1379.

11. Case 104/75*, de Peijper*, EU:C:1976:67, para 15.

12. Case C-222/18*, VIPA*, EU:C:2019:751, para 71; Case C-296/15*, Medisanus*, EU:C:2017:431, para 82; Case C-141/07*, Commission* v. *Germany*, EU:C:2008:492, para 51. This has been reaffirmed in a rather different context in a case on professional qualifications, Case C-96/20*, Ordine nazionale dei biologi*, EU:C:2021:191, para 36.

13. Art. 26 TFEU.

ECJ gradually reframed health protection from a "property or interests protected by Article 36"[14] to become one of "the assets and interests protected by the Treaty".[15] This shift has reflected the evolutions occurring in the text of the EU Treaties. The Maastricht consolidated version of the Treaty on the European Community already assigned to health protection a more visible place.[16] The Treaty of Lisbon further reinforced its standing across the Union policies. More specifically, the Maastricht language of "contributing" to a high level of human protection was progressively strengthened with a thicker mandate: Article 168(1) TFEU now reads that a "high level of human health protection *shall be ensured* in the definition and the implementation of *all* Union policies and activities".[17]

In the wake of the COVID-19 pandemic, it is not surprising that the overarching reading of health protection was embraced and developed by the Commission with a view to preserving the unity and the viability of the EU internal market. As perceptively noted by some commentators, the Commission proposed a reading of the EU Treaty edifice whereby the proportionality of derogations pursuant to Article 36 TFEU would be assessed "*at Union level*".[18] In other words, the legality assessment of the restrictive measures would no longer be carried out "having as a term of reference the territory and the population of the single State adopting the measure".[19] It would extend, instead, to the population and territory of the EU in its entirety.[20] Indeed, calling for the respect of the principle of solidarity between

14. Case 215/87*, Schumacher* v. *Hauptzollamt Frankfurt am Main-Ost*, EU:C:1989:111, para 17.

15. Joined Cases C-171 & 172/07*, Apothekerkammer des Saarlandes*, EU:C:2009:316, para 19. In the words of Azoulai, the "Court turned discrete national interests into essential common goods protected by the Union and the Treaty as a whole": Azoulai, "The European Court of Justice and the duty to respect sensitive national interests" in de Witte, Muir and Dawson (Eds.), *Judicial Activism at the European Court of Justice: Causes, Responses and Solutions* (Edward Elgar, 2013), p. 181.

16. Art. 129 EC (Maastricht consolidated version), O.J. 1992, C 191.

17. Emphasis added. Some commentators have attributed the shift to Case C-180/96 R, *UK* v. *Commission*, EU:C:1998:192, where the Court "implicitly recognized the centrality of human health to all Union activity on the basis of its reading of the Treaty texts as a whole": Hervey and de Ruijter, "The dynamic potential of European Union health law", 11 EJRR (2020), 726, at 730. See also Bartlett and Naumann, "Reinterpreting the health in all policies obligation in Article 168 TFEU: The first step towards making enforcement a realistic prospect", 16 *Health Economics, Policy and Law* (2021), 8.

18. Purnhagen et al., "More competences than you knew? The web of health competence for European Union action in response to the COVID-19 outbreak", 11 EJRR (2020), 297, at 305 (emphasis in the original).

19. Mariani, "The EU market in times of a global state of emergency: Internal and external trade barriers in the age of pandemics", 48 LIEI (2021), 5, at 10.

20. Ibid. See also COM(2020)112, Commission Communication, "Coordinated economic response to the COVID-19 outbreak", 13 March 2020.

the Member States, the Commission deterred the maintenance in force of national restrictions liable to jeopardize the integrity of internal market for goods.[21] Furthermore, the Commission clearly indicated that the proportionality test for national measures taken under Article 36 TFEU would need to ensure adequate supply of essential products and to prevent shortages "*throughout the EU*".[22]

The Commission's stance and rhetoric at the inception of the COVID-19 crisis was premised on the consideration that "[u]nilateral national restrictions to the free movement of essential supplies to the healthcare system [would] create significant barriers and affect dramatically Member States' capacity to manage the COVID-19 outbreak". EU-wide "internal market rules" would instead "support Member States by ensuring efficiency".[23] By framing the EU internal market as a domestic market,[24] the Commission hence rendered the justification of discrete national restrictive measures more difficult to maintain under proportionality terms.[25]

The understanding of EU rules as governing the efficient allocation of resources resonates with the ECJ's case law on health protection and free movement of goods. For instance, in *Medisanus* the Court upheld a mutually reinforcing Union-wide understanding of autonomy/self-sufficiency and solidarity.[26] By finding national origin requirements in tender specifications of a public contract at issue disproportionate,[27] the Court discouraged a purely national conception of solidarity.[28] Internal market rules on free movement of goods would provide for a better allocation of resources in pursuing public

21. European Commission, "COVID-19, 'Guidelines for border management measures to protect health and ensure the availability of goods and essential services'", C(2020)1753 final, 16 March 2020.

22. European Commission "National measures relating to medical products and devices and of personal protective equipment", Annex II to Commission Communication COM(2020)112 cited *supra* note 20.

23. COM(2020)112 cited *supra* note 20, p. 3.

24. On the conception of the Union market as a domestic market, see Case 270/80, *Polydor Limited* v. *Harlequin Records*, EU:C:1982:43, para 16.

25. In Annex II, cited *supra* note 22, the Commission clarified that: "[a] simple export ban alone cannot meet the legal requirement of proportionality. . . . an export ban would not avoid stockpiling or purchasing of goods by persons who have no or limited objective need and would not ensure channelling the essential goods where they are most needed, i.e. infected persons or health institutions and staff. Measures without a clearly identified scope restricted to actual needs, a solid rationale and/or a limited duration may increase the risk of scarcity and therefore are very likely to be disproportionate", at p. 4. Note also that the Commission appeared to threaten Member States with infringement procedures; Bayer et al., "EU moves to limit exports of medical equipment outside the bloc", *Politico* (15 March 2020).

26. See Case C-296/15, *Medisanus*, para 97.

27. Ibid., para 28.

28. Ibid., para 97.

objectives like that of health protection, while fostering solidarity across the Union.

The Commission's rhetoric and its initial framing of the need for EU-wide measures to face the pandemic appeared thus in line with the canonical understanding of the internal market rules as guaranteeing an appropriate allocation of resources. Yet in the more acute phases of the pandemic, the EU legal framework underwent a paradigmatic shift. Internal market mechanisms were mobilized and overhauled to harness the economic leverage of the Union in a way that favoured executive centralization and a more active intervention of public powers in the economy. This active exercise of EU executive powers was oriented towards the attainment of the EU's strategic objective of autonomy with regard to the purchase, distribution, and free movement regulation of critical goods and vaccines.

3. Internal: Joint procurement and advance purchase agreements

The internal dimension of EU operational autonomy has taken the form of the joint procurement and purchase of medical equipment, critical resources, and vaccines. The market power of the Union[29] was expressed through the deployment of the Commission's executive functions. The unitary framework provided by Union law was conducive to directing and coordinating the actions of the EU and its Member States. The recourse to Joint Procurement Agreements (JPAs) has been part of the internal development of EU operational autonomy. As a legal instrument, the JPA is contemplated in Article 5 of Decision 1082 /2013/EU on serious cross-border threats to health.[30] The provision at issue reads that the "institutions of the Union and any Member States which so desire may engage in a joint procurement procedure … with a view to the advance purchase of medical countermeasures for serious cross-border threats to health".

The legal basis of the Decision can be found in Article 168(5) TFEU. In a note drafted well before the outbreak of the pandemic, the Commission had clarified that JPAs are not treaties regulated by international law, but should be considered as a budgetary implementing measure of a legislative measure, namely the Decision on cross-border threats to health.[31] The Commission

29. Damro, "Market power Europe", 19 *Journal of European Public Policy* (2012), 682; Bradford, *The Brussels Effect: How the European Union Rules the World* (OUP, 2020).

30. Decision 1082/2013/EU of the European Parliament and of the Council on serious cross-border threats to health, O.J. 2013, L 293.

31. European Commission, "Explanatory note on the joint procurement mechanism", Luxembourg (Dec. 2015), pp. 8–9. See in particular Art. 165(2) Regulation (EU, Euratom)

posited that "[e]xecution of the JPA does not involve the exercise of the public law powers related to health policy conferred under Article 168 TFEU".[32] Indeed, the JPA is regarded as "an administrative arrangement concerning purchasing, which is within the executive functions of the Commission, and thus Article 17 TFEU. In such situations the Commission is not acting under its policy-making public law powers at all, but simply performing its executive/management functions".[33] This rather categorical downplaying of the exercise of EU executive powers as separated from public law powers appears to indicate an initial Commission reticence in acknowledging the political salience of its executive actions. As will be contended in the development of this section, such a reticence has been supplanted by a more robust political posture in the exercise of executive powers related to the advance purchase and distribution of vaccines.

JPAs have been used for the purchase of critical goods and Personal Protective Equipment (PPE).[34] They mobilized legal instruments of EU law in areas such as public health, where the Union has mainly supportive or complementary competences.[35] They contributed to fostering the unity of the Union's response under the framework and the guarantees of EU law. JPAs are subject to the judicial review by the Court of Justice[36] and they comply with the main principles and requirements of good administration applicable to contracts financed in whole or in part by the budget of the Union,[37] namely the principles of transparency, proportionality, equal treatment, and non-discrimination.[38] The recourse to JPAs thus limited the perils of the "deactivation" of standard procurement rules, which occurred especially

2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, O.J. 2018, L 193.

32. Explanatory note, ibid., p. 8.

33. Ibid., pp. 8–9.

34. See Contract award notice 2020/S 100-238631, 13 May 2020; Contract Award Notice 2020/S 100- 238632 of 15 May 2020; Contract award notice 2020/S 224-549596 of 5 Nov. 2020.

35. See Art. 6 TFEU.

36. See in particular Arts. 272 and 273 TFEU. See also Arts. 40 to 43 of the draft JPAs, available at <health.ec.europa.eu/system/files/2016-11/jpa_agreement_medicalcountermeasures_en_0.pdf>. Although the Court of Auditors has noted that, for EU procurements: "Procedures before the EU Courts take a long time and compensation for alleged damages is rarely granted", European Court of Auditors, "The EU institutions can do more to facilitate access to their public procurement", Special Report No. 17 (Publications Office, 2016).

37. Art. 5 of Decision 1082/2013/EU, cited *supra* note 30, clarifies that the JPAs are subject to the financial rules applicable to the budget of the Union.

38. These are the principles detailed in Art. 160 of Regulation (EU, Euratom) 2018/1046, cited *supra* note 31.

during the initially fragmented national responses.[39] In fact, although allowing for more flexibility during the outbreak of the crisis, the bypassing of procedural safeguards of standard procurement rules by national administrations has been detrimental to the quality of the purchases.[40] As McEvoy and Ferri put it, arguably the "procedures set out in the JPA have facilitated a balance between promoting competition in the marketplace and securing reasonable-cost and high-quality medical supplies and services".[41]

The internal dimension of EU operational autonomy was more clearly developed in the Commission's actions relating to the purchase of COVID-19 vaccines. The purchase initiatives consolidated EU operational autonomy as a framework constructed under the Commission's executive powers coordinating the joint actions of the EU and its Member States. On the legal plane, the conclusion of Advanced Purchase Agreements (APAs) of COVID-19 vaccines was facilitated by the revised provisions of the Emergency Support Instrument Regulation.[42] The Regulation finds its legal basis in the EU solidarity clause enshrined in Article 122(1) TFEU. The revision of the Regulation was undertaken with a view to adapting the EU's budgetary rules to the needs that had arisen from the pandemic.[43] The memorandum to the Commission proposal justified the choice of the instrument of a regulation for general and immediate application and for its potential of deploying a "swift, uniform and Union-wide financial assistance mechanism".[44] Several types of financial intervention and implementing procedures are envisaged therein to increase the EU's operational capacity. In particular, Article 5(b) of the Regulation provides for "procurement by the

39. Sanchez-Graells, "Procurement in the time of COVID-19", 71 *Northern Ireland Law Quarterly* (2020), 81, at 82. The use of negotiated procedure without prior publication is envisaged in Art. 32 of Directive 2014/24/EU of the European Parliament and of the Council on public procurement and repealing Directive 2004/18/EC, O.J. 2014, L 94. See on this, European Commission, "Guidance from the European Commission on using the public procurement framework in emergency situation related to COVID-19 crisis", (C/2020/2078), O.J. 2020, C 108 I.

40. Halloran, "Procurement during a public health crisis: The role of the European Union", 32 *Irish Studies in International Affairs* (2021), 67, at 74.

41. McEvoy and Ferri, "The role of the Joint Procurement Agreement during the COVID-19 pandemic: Assessing its usefulness and discussing its potential to support a European health Union", 11 EJRR (2020), 851, at 859.

42. Council Regulation (EU) 2016/369 on the provision of emergency support within the Union, O.J. 2016, L 70.

43. Council Regulation (EU) 2020/521 activating the emergency support under Regulation (EU) 2016/369 and amending its provisions taking into account the COVID-19 outbreak, O.J. 2020, L 117. See in particular Recital 6 and Art. 2 therein clarifying the derogations to Regulation 2018/1046, cited *supra* note 31.

44. COM(2020)175 final, European Commission, Proposal for a Council Regulation activating the emergency support under Council Regulation (EU) 2016/369 of 15 March 2016 and amending its provisions in respect of the COVID-19 outbreak.

Commission on behalf of Member States based on an agreement between the Commission and the Member States".[45] The EU-wide APAs of COVID-19 vaccines were concluded under this provision.

The overhaul of the ESI Regulation was carried out in light of the fact that other ancillary responses, including the equipping of the RescUE mechanism[46] with medical stockpiling capacities,[47] were considered insufficient. According to the Commission, the pre-existing Union instruments did "not allow sufficient response or make it possible to address effectively the large-scale consequences" of the COVID-19 crisis.[48] Through the Emergency Support Instrument, the EU earmarked €2.7 billion to finance the COVID-19 response.[49] These funds included actions for transporting patients and medical staff within the EU, procuring essential medicines, researching and producing treatments and vaccines, developing purchasing and distributing testing supplies.[50] The Commission stated that it stood "ready to commit a significant proportion of those funds to activities" aimed at "maximi[zing] chances of arriving at a viable vaccine for the EU and the world in the shortest time possible".[51] This indicated the Union's intention to boost its industrial capacity and responsiveness, carving out a greater space for the EU public powers in pursuing strategic objectives.[52]

The amendment of the ESI Regulation for the joint purchase of vaccines was thus motivated by the wish to harness the full potential of Union market power with a view to "securing rapid, sufficient and equitable [COVID vaccine] supplies for Member States".[53] The design of the EU-wide response aimed at internalizing externalities originating from the interdependences of

45. Art. 4(5)b instead referred to the joint procurement in the framework of Art. 165(2) of Regulation 2018/1046, cited *supra* note 31.

46. Commission Implementing Decision (EU) 2019/570 laying down rules for the implementation of Decision No. 1313/2013/EU of the European Parliament and of the Council as regards rescEU capacities and amending Commission Implementing Decision 2014/762/EU (notified under document C(2019)2644), O.J. 2019, L 99.

47. See Art. 1(2) of Commission Implementing Decision (EU) 2020/414 of 19 March 2020 amending Implementing Decision (EU) 2019/570 as regards medical stockpiling rescEU capacities (notified under document C(2020) 1827), O.J. 2020, L 82 I/1.

48. See Recital 4 Council Regulation (EU) 2020/521, cited *supra* note 43.

49. COM(2020)245, Commission Communication, "EU Strategy for COVID-19 vaccines", 17 June 2020, p. 3.

50. European Civil Protection and Humanitarian Aid Operations, "Emergency Support Instrument – Factsheet", version of 7 Sept. 2021, p. 2.

51. COM(2020)245, cited *supra* note 49, p. 3.

52. See COM(2021)66 final, Commission Communication, "Trade policy review – An open, sustainable and assertive trade policy", 18 Feb. 2021, in particular with respect to "open strategic autonomy" and the resilience of the value chains.

53. See Recital 2 of Commission Decision approving the agreement with the Member States on procuring COVID-19 vaccines on behalf of the Member States and related procedures, C(2020)4192 of 18 June 2020.

the economies of the Member States and their societies.[54] The Commission's discourse continually stressed that the "European approach would avoid competition among Member States" and would foster "solidarity between all Member States, irrespective of the size of their population and their purchasing power". Moreover, the "pan-EU approach [would] increase the EU's leverage when negotiating with industry [while] combining the scientific and regulatory expertise of the Commission and the Member States".[55] The APAs of vaccines were devised within the context of this unitary framework for the exercise of the EU's executive powers.

The APAs represented a turning point in structuring the relations between the EU and its Member States. In addition to the collective purchase already envisaged in JPAs, the APAs granted the Commission a role in the distribution of vaccines.[56] The APAs were concluded on the basis of an agreement between the Commission and the Member States which enabled the Commission to conduct the relevant procurement procedures on behalf of Member States. The APAs would "provide the right – or under specific circumstances the obligation – to Participating Member States to buy a specific number of vaccine doses within a given timeframe and at a given price".[57] The initial distribution key proposed by the Commission was based on doses proportional to the population of each Member State.[58] The Member States subsequently decided to include some latitude for adapting to the epidemiological situation and the vaccination needs of each country. In that way, vaccine doses envisaged for a Member State deciding not to benefit from a part of them would be distributed among the other interested Member States.[59]

The centralization of negotiation, purchase and distribution of vaccines signals a development away from the free movement rationales underpinning EU rules. The progressive instrumentalization of internal market mechanisms, which occurred in the implementation the executive actions in the wake of the COVID-19 outbreak, is different from the "negative" understanding of integration premised on the removal of (national) barriers to trade. In fact, this

54. COM(2020)245, cited *supra* note 49, p. 2.

55. Ibid., p.3.

56. Brooks and Geyer, "The development of EU health policy and the Covid-19 pandemic: Trends and implications", 42 Journal Eur. Int. (2020), 1057, at 1061.

57. Recital 3 of Commission Decision, C(2020)4192, cited *supra* note 53.

58. Commission Decision, C(2020)4192 cited *supra* note 53, Annex II: Agreement between the Commission and Member States on procuring COVID-19 vaccines, Annex to the Commission Decision on approving the Agreement with Member States on procuring COVID-19 vaccines on behalf of the Member States and related procedures.

59. European Commission, "Statement on the methodology used to determine the allocation of doses of vaccines under the Advance Purchase Agreements", Brussels, 13 March 2021.

new vision of the internal market is not predicated on the "decentralized" economic model based on market access and the notion of competitive federalism of market players;[60] nor is it based on "positive" integration and a "centralized" model leading to harmonization of law and standards.[61] It is instead a vision of a political entity where the EU's economic weight and internal market mechanisms can be leveraged to achieve the political objective of autonomy in the purchase and distribution of critical goods and vaccines. This vision is intended to enhance the EU's capacity to compete at a global level to secure essential resources, while reducing competition among EU Member States.

The evolution of this centralized preparedness capacity of the Union to respond to health crises has been progressively institutionalized to tackle other health threats. On 16 February 2021, the European Health and Digital Executive Agency was established.[62] On 14 June 2022, the agency signed a contract on behalf of the European Commission's Health Preparedness and Response Authority (HERA) for procuring vaccines for the Union in response to the monkeypox outbreaks. The purchase inaugurated the use of the EU budgetary powers channelled through the EU4Health programme[63] to purchase vaccines for the Member States.[64] This signals a further development towards the centralization of the EU's executive budget powers in the health domain, consolidating procedures and instruments introduced in the EU in the context of the COVID-19 crisis.

Political elements, thus, are being more overtly attached to the exercise of public powers to direct and intervene in the market.[65] The deployment of ESI and EU4Health funds to boost the EU's industrial capacity, and the active role of the Commission in procuring and regulating critical resources and vaccines are an example of this trend. This does not mean that the traditional decentralized understanding of the internal market is not premised on a

60. Barnard, *The Substantive Law of the EU: The Four Freedoms*, 6th ed. (OUP, 2019), at p. 22. See on this also Barnard and Deakin, "Market access and regulatory competition" in Barnard and Scott, *The Law of the Single European Market: Unpacking the Premises* (Bloomsbury Publishing Plc, 2002).

61. Barnard (2019), ibid., Ch. 14.

62. In accordance with Council Regulation (EC) 58/2003; See Commission Decision delegating powers to the European Health and Digital Executive Agency, C(2021)948 final of 12 Feb. 2021.

63. Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health (EU4Health Programme) for the period 2021–2027, O.J. 2021, L 107.

64. European Commission, "HERA secures vaccines for EU Member States in response to the monkeypox outbreaks", Press Release (14 June 2022).

65. See *The Economist*, "The world is entering a new era of big government" (20 Nov. 2021). For a broader perspective see also Mazzucato, *The Entrepreneurial State: Debunking Public vs. Private Sector Myths*, (Penguin, 2018).

political choice: that of competition among market players. Yet, the political tenor of EU operational autonomy is more evident in light of the greater freedom and space accorded to EU public powers in pursuing strategic political objectives. In this understanding, the unitary legal framework of EU operational autonomy is not severable from the political choice of unity, intended to harness the EU's economic and political weight. As a matter of fact, the ESI (amended) Regulation was precisely intended to "derive maximum benefit from the potential of the internal market in terms of economies of scale and risk-benefit sharing".[66]

The rationales underlying the combination of the legal and the political in the unitary purchase framework have been well captured in the different context of the more recent energy crisis triggered by the war in Ukraine. Here, the European Council has singled out how the common purchase of gas would grant the possibility to make "optimal use of the *collective political and market weight* of the European Union and its Member States".[67] Similarly to what happened with the vaccines, also in this domain, the Commission is laying the foundations for a "voluntary *operational* 'joint purchasing mechanism' responsible for negotiating and contracting on behalf of participating Member States of the aggregate gas demand and competitive release to the market", with a view to "leveraging the power of the European market".[68]

The internal dimension of EU operational autonomy established a venue for joint actions of the EU and its Member States under the unitary framework of EU law. Although the Commission was "exclusively responsible for the procurement and the conclusion of the APAs",[69] Member States have been closely involved in the governance of the process. In addition to the possibility of the participating Member States to top up fundings, in case of insufficient financing under the ESI,[70] experts from Member States with production capacity assisted the Commission in a "joint negotiation team". Furthermore, a Steering Board, including representatives of the Member States, was envisaged to assist and provide guidance for the governance of the negotiation process of APAs.[71] The relation between the EU institutions and the Member States was governed by the principle of loyal cooperation. This was expressed

66. Recital 15 Regulation (EU) 2020/521, cited *supra* note 43.
67. European Council Conclusions, Brussels, 25 March 2022, p. 7 (emphasis added).
68. COM(2022)230, Commission Communication, "REPowerEU Plan", 18 May 2022, p. 4 (emphasis added).
69. Art. 6 Agreement between the Commission and Member States, cited *supra* note 58.
70. Ibid., Annex, p. 4.
71. Ibid.

inter alia by the Member States' obligation not to negotiate separately with the same manufacturer after the APA has been signed.[72]

The EU operational autonomy framework enabled the Union to pursue its strategic objectives by harnessing the potential of the internal market acting as one. Several APAs have been concluded by the Commission in light of the European Medical Agency (EMA) recommendations.[73] It is worth mentioning that the initial results of the implementation of the contract were rather dismal. Orders on the three vaccines were placed later than by the US and the UK, leaving the EU at a comparatively disadvantaged position in the delivery of scarce stocks.[74] As admitted by the European Commission President, there was a rather unwarranted optimism in the production capacity, and the timely delivery of the orders was taken for granted.[75] Notwithstanding the initial poor results, the EU managed to achieve its procurement and vaccination targets in the summer of 2021.[76] Significantly, as the Commission's President put it, the joint purchase of vaccines served the aim of protecting the internal market and EU unity.[77] This appears to have laid the foundations for a legal framework governing the Union's purchase of critical and scarce resources, also in other domains.

4. External: EU-wide export authorization mechanisms

The safeguard of the unity of the EU internal market and the use of its economic and political leverage was also made possible by the development of the external dimension of EU operational autonomy. At the inception of the COVID crisis, the rationale for the progressive removal of discrete national protective measures regarding PPEs was the adoption of an EU-wide export

72. Art. 7 Agreement between the Commission and Member States, cited *supra* note 58.

73. See e.g. AstraZeneca AB3: C(2020)5707 final; Sanofi Pasteur S.A. and Glaxosmithkline Biologicals S.A4: Commission APAs COVID final; Janssen Pharmaceutica NV5: C(2020)7032 final; Pfizer Inc. and BioNTech Manufacturing GmbH6: C(2020)7950 final; CureVac AG7: C(2020)8154 final; and Moderna Switzerland GmbH: C(2020)8434 final. See for the references, Commission Decision of 15 Dec. 2020 on implementing Advanced Purchase Agreements on COVID-19 vaccines.

74. Markus et al., "The impact of COVID-19 on the internal market", European Parliament (26 Feb. 2021), p. 45.

75. European Commission, Speech by the President, "The COVID-19 vaccination strategy", Brussels (10 Feb. 2021).

76. European Commission, Statement by the President "A new milestone in the EU vaccines strategy", Brussels (27 July 2021).

77. Speech by the President of the Commission, cited *supra* note 75. The President maintained: "I don't even want to imagine what it would have meant if some large Member States had secured the vaccine while the rest went empty-handed. What would that have meant for our internal market, and for European unity?".

authorization mechanism.[78] Similarly to the internal dimension of EU operational autonomy, the external dimension was developed through the exercise of the Commission's executive powers. Specifically, the authorization mechanism was introduced pursuant to the Commission implementation powers of Article 291 TFEU. The legislative instrument at the basis of the relevant Commission Implementing Regulations is the EU Regulation on common rules for export.[79] Article 5 of this Regulation envisages the adoption of protective actions "to prevent a critical situation from arising on account of shortage of essential products, or to remedy such a situation", giving the Commission the powers to adopt these measures. In turn, the EU Regulation on export rules is based on Article 207(2) TFEU, and therefore on the exclusive competences under the EU's trade policy. The role of the Member States is still significant, given that the Commission implementing powers are exercised in the framework of the Comitology Regulation.[80]

The first Commission Implementing Regulation on export authorization laid down uniform rules for PPE export.[81] Member States' national administrations would apply the measure exercising their discretion within the parameters set by the Commission.[82] While in the original Implementing Regulation on PPE, no active role was granted to the Commission in the export authorization framework, a subsequent amendment of the scheme contemplated a clearing-house established by the Commission, to be contacted before granting the authorization.[83] The revised procedural aspects

78. Indeed, the Commission Communication "Guidance note to Member States related to Commission Implementing Regulation (EU) 2020/402 making the exportation of certain products subject to the production of an export authorisation", of 20 March 2020, O.J. 2020, C 91 I/10, made it clear that the Implementing Regulation was adopted with "the understanding that Member States should revoke any restrictive national actions taken, formally or informally, concerning either exports to third countries or trade between the Member States within the Single Market".

79. Regulation (EU) 2015/479 of the European Parliament and of the Council on common rules for exports, O.J. 2015, L 83.

80. Regulation (EU) 182/2011 of the European Parliament and of the Council of 16 Feb. 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (Comitology Regulation), O.J. 2011, L 55. In particular, Arts. 5 and 6 of Regulation (EU) 2015/479, cited *supra* note 79, which were used as legal basis for the Commission Implementing Regulations on export control make *renvois* to Art. 3 of the Comitology Regulation and the relevant comitology committees.

81. Commission Implementing Regulation (EU) 2020/402 making the exportation of certain products subject to the production of an export authorization, as last amended by Commission Implementing Regulation (EU) 2020/426, O.J. 2020, L 84I/1.

82. See, *inter alia*, ibid., Art. 2(3) and Annex II therein.

83. Recital 16 of Commission Implementing Regulation (EU) 2020/568 making the exportation of certain products subject to the production of an export authorization, O.J. 2020, L 129.

also envisaged the obligation for the Member States assessing the authorization request to inform the Commission.[84] The application of the mechanism resulted in 95 percent of export authorization being granted.[85]

A similar mechanism was introduced for regulating the export of vaccines. In this case, in addition to the need to regulate the export of scarce resources, the adoption of the authorization mechanism was deemed necessary in light of the indication that certain vaccine manufacturers would not be able to provide the pledged quantities of vaccines produced in the Union, notwithstanding the significant financial support accorded to them to increase production.[86] The ensuing export authorization measures were thus intended to "remedy a critical situation and to ensure transparency" and to secure "adequate supplies in the Union to meet the vital demand".[87]

The export authorization mechanisms for vaccines lasted substantially longer than the ones on PPE: from January to December 2021. The Commission Implementing Regulations were extended and amended several times. The first Implementing Regulation (EU) 2021/111 of 29 January 2021 was adopted on the basis of Article 5 of the EU Regulation on common rules for export. Its implementation relied on the authorities of the Member States. The only refusal occurred in Italy and concerned a request from AstraZeneca for authorization of export of 250,700 doses of vaccine destined for Australia. While previous authorization requests had been accepted by the Italian authorities, in the case at issue, the Italian Foreign Ministry sent a non-authorization proposal to the European Commission on 26 February 2021. The motives cited in the refusal were:

> "the fact that the country of destination of the supply is considered 'non-vulnerable' within the meaning of the Regulation; the ongoing

84. See Arts. 2(7) and 3(5) of Commission Implementing Regulation (EU) 2021/111 making the exportation of certain products subject to the production of an export authorization, O.J. 2021, L 31I/1.

85. European Commission, "Coronavirus: Requirement for export authorisation for personal protective equipment comes to its end", News Archives, Brussels (26 May 2020), available at <ec.europa.eu/newsroom/trade/items/677985>; see also European Commission, "Information by the Commission on granted and rejected export authorisations in the period of 26 April to 25 May 2020" (26 May 2020), available at <trade.ec.europa.eu/doclib/docs/2020/may/tradoc_158735.pdf>.

86. Recital 3 Commission Implementing Regulation (EU) 2021/111, cited *supra* note 84 (emphasis added). In addition to the Emergency Support Instrument, the EU mobilized other resources to support vaccine producers particularly through the European Investment Bank and its financial instruments, among which Horizon 2020 InnovFin, the European Fund for Strategic Investment (EFSI), and the forthcoming InvestEU.

87. Recital 5 of Commission Implementing Regulation (EU) 2021/111, cited *supra* note 84.

> shortage of the vaccines in the EU and Italy and the delays in the supply of vaccines by AstraZeneca to the EU and Italy; the large number of vaccine doses referred to in the request . . . compared to the quantity of doses so far supplied to Italy and, more generally, to EU countries".[88]

The Commission "did not disagree" to the proposal to deny the authorization.[89] This was the single instance of refusal in a set of more than 3,000 authorizations requested in the EU for 57 destination countries.[90]

The motives of refusal adduced by the Italian Government informed the amendments of the vaccine authorization mechanism through Commission Implementing Regulation (EU) 2021/442 of 11 March 2021,[91] adopted on the basis of Article 6 of the EU Regulation on common rules of export.[92] The amendment was motivated by the necessity to secure sufficient supply to the EU in light of the risk that "vaccines produced or packaged in the Union are exported, especially to non-vulnerable countries in potential breaches of contractual commitments entered into by pharmaceutical industries".[93] Subsequent developments of the EU export authorization mechanism occurred with the Commission Implementing Regulation (EU) 2021/521 of 24 March 2021. The initial design of the mechanism envisaged that the national competent authority of the Member State would "deliver an export authorization only where the volume of exports [would not pose] a threat to the execution of the Union APAs concluded with vaccines manufacturers".[94] The amendments progressively articulated the criteria that ought to inform the

88. Italian Government, Ministero degli Affari Esteri e della Cooperazione Internazionale, "Request for authorization to export COVID-19 vaccines filed by AstraZeneca", Press Release (4 March 2021).

89. European Commission, Request for information, Gestdem 2021/7336, reply of 28 Oct. 2021. The Italian Foreign Ministry noted in a slightly different wording that the Commission "approved" Italy's proposal to deny the authorization. See also Press Release, ibid.

90. Request for information, ibid.

91. Commission Implementing Regulation (EU) 2021/442 of 11 March 2021 making the exportation of certain products subject to the production of an export authorization, O.J. 2021, L 85.

92. Art. 6(1) of Regulation (EU) 2015/479 cited *supra* note 79, reads that: "[w]here the interests of the Union so require, the Commission may, acting in accordance with the examination procedure referred to in Article 3(2), adopt appropriate measures: (a) to prevent a critical situation from arising owing to a shortage of essential products, or to remedy such a situation"; this allowed both for the extension of the export control mechanism originally envisaged for a period of 6 weeks pursuant to Art. 5 of the Regulation and to amend the authorization scheme.

93. Recital 3, Commission Implementing Regulation (EU) 2021/442, cited *supra* note 91.

94. Art. 1(4) Regulation (EU) 2021/111, cited *supra* note 84.

assessment for allowing the export authorization. They clarified that Member States would grant the authorization insofar as it did not "pose a threat to the security of supply within the Union".[95] Moreover, the criteria included considerations of reciprocity in gauging "whether the country of destination of the export restricts its own exports to the Union of goods [vaccines and active substances] covered by Implementing Regulation (EU) 2021/442, or of the raw materials from which they are made".[96] The criteria further prescribed an assessment of the epidemiological situation, the vaccination rates, and the availability of vaccines and active substances in the country of destination of the export.[97] While in March 2021, the amendments to the export authorization mechanism mainly focused on the conditions for granting the export authorization,[98] those of May 2021 concerned the geographical application of the exemptions.[99] The vaccine export authorization mechanism was extended twice until 31 December 2021.[100]

The joint participation of the EU and its Member States, defines the export authorization framework as a "mixed administrative proceedings", involving both EU and national authorities in multiphase processes.[101] The role of the Member States in the mechanism was not limited to the application of the authorization mechanism, it also entailed the design of the Commission Implementing Regulation. Articles 5 and 6 of the EU Regulation on common rules for export, on which the export mechanism is based, refer to the Comitology Regulation and its examination procedure for the adoption of protective measures.[102] The procedure at issue envisages that export rules are devised by the Commission under the "assistance" of a committee composed of representatives of the Member States,[103] namely the Committee on

95. Art. 2(1)b Commission Implementing Regulation (EU) 2021/521, of 24 March 2021 making specific arrangements to the mechanism making the exportation of certain products subject to the production of an export authorization, O.J. 2021, L 104.

96. Ibid., Art. 2(2)a.

97. Ibid., Art. 2(2)b.

98. See Commission Implementing Regulations (EU) 2021/442, cited *supra* note 91, and (EU) 2021/521, cited *supra* note 95.

99. Commission Implementing Regulation (EU) 2021/734, O.J. 2021, L 158. The geographical application will be addressed more thoroughly in the next section.

100. Commission Implementing Regulation (EU) 2021/1071 of 29 June 2021, O.J. 2021, L 230; Commission Implementing Regulation (EU) 2021/1728 of 29 Sept. 2021 related to the mechanism making certain products subject to the production of an export authorization, O.J. 2021, L 345.

101. della Cananea, "The European Union's mixed administrative proceedings", 68 *Law and Contemporary Problems* (2004), 197.

102. See Arts. 5 and 6 of Regulation (EU) 2015/479, cited *supra* note 79, and Art. 5 of Regulation (EU) 182/2011, cited *supra* note 80.

103. Art. 3(2) Regulation (EU) 182/2011, cited *supra* note 80.

Safeguards and Export Control.[104] The comitology procedure may thus be regarded as a partial antidote[105] to the perils of executive centralization ensuing from the enhanced role of the Commission, particularly in areas of exclusive EU competences, such as trade.

An inquiry into the comitology committee procedures informing the vaccine export mechanism reveals both Member States' involvement in the procedures and elements of contestation. The text of the last Commission Implementing Regulation signifies that there was a recourse to the Appellate Committee, which delivered no opinion.[106] The referral to the Appellate Committee[107] may imply that the measure had been contested.[108] This appeared to be due to the fact that there was "no longer . . . the need for export controls [in times when] the EU has sufficient capacity to meet its vaccine demand".[109] According to the comitology procedures, the Appellate Committee is mobilized when the Commission deems that the implementing act is still necessary, either after the Committee on Safeguards and Export Control delivers a negative opinion[110] or when the act covers specific subject areas, including health protection, and the said Committee delivers no opinion.[111] It has not been possible to ascertain whether the Committee on Safeguards and Export Control delivered a negative opinion or no opinion at all in the case at issue.[112] Nevertheless, the fact that the Appellate Committee delivered no opinion still left the Commission the possibility to bring forward the implementing act, which was in fact adopted.[113] After the comitology

104. See European Commission, Comitology Register, Committee on Safeguards and Common Rules for Exports, "Written consultation regarding the amendment of Implementing regulation on export authorisations for vaccines" of 10 Sept. 2021, CMTD, 1421.

105. Along similar lines, Editorial Comments, op. cit. *supra* note 3, ask whether "the perceived structural weakness of the Union" may be regarded as "an antidote for Europeanism", 321.

106. Recital 8 of Commission Implementing Regulation (EU) 2021/1728, cited *supra* note 100.

107. See Art. 3(2) Regulation (EU) 182/2011, cited *supra* note 80.

108. The Committee on Safeguards and Export Control delivers its opinion by majority of the Member States as defined in Arts. 16(4) and (5) TEU and 238(3) TFEU. See Art. 5(1) of Regulation (EU) 182/2011, cited *supra* note 80.

109. Follain and Nardelli, "EU nations split over need to renew vaccine export controls", *Bloomberg.com* (16 Sept. 2021).

110. Art. 5(3) Regulation (EU) 182/2011, cited *supra* note 80.

111. Ibid., Art. 5(3–4).

112. European Commission, reply to request for access to documents – GestDem 2021/7711, "Cover letter asking members for vote in written consultation" in the Comitology Committee; the document requested has not been disclosed given that it was considered liable to "undermin[e] the decision-making process of the Commission in the context of the Committee on Safeguards and Common rules for exports".

113. Ibid., and Art. 6(3) Regulation (EU) 182/2011, cited *supra* note 80.

incident, the export authorization mechanism was supplemented by a looser export monitoring mechanism, in place since January 2022.[114]

The legal framework of both the internal and external dimensions of EU operational autonomy pertains to the exercise of the Commission's executive powers and cuts across the spectrum of EU competences. Internally, the exercise of the Commission's budgetary powers has been used for common purchases in the domain of health protection, which mainly fall under EU coordinating and supporting competence.[115] Externally, the EU-wide export control mechanisms were adopted under the exclusive competence framework of EU trade policy.[116]

The competences distinction appears thus less salient in the exercise of the EU executive powers in the EU operational autonomy framework. This framework, also in the realm of trade policy exclusivity, is based on mechanisms providing for the joint participation of the EU and its Member States. In the external facet of EU operational autonomy, the role of Member States has been significant in the implementation of the EU-wide export authorization mechanism designed by the Commission. Moreover, Member States were part of the mixed administrative proceedings which referred to national authorities for the ultimate choice of the granting of the export authorization. Furthermore, the Member States assisted the Commission in the design of the mechanism through the comitology committees. This illustrates how, in the domains of EU exclusive competences, the autonomy of the legal framework is not manifested in the sole action of EU institutions, but is operationalized in mixed venues, featuring the joint involvement of EU institutions and the Member States.[117]

In the internal dimension, the political tenor of the EU operational autonomy framework has been more visible: separate procurement and purchase mechanisms by Member States would have been possible. Yet, a close scrutiny of the external dimension supports the argument that even in the EU-wide export authorization mechanism, unity as a feature of the legal framework is hardly severable from unity as a policy choice, notwithstanding the exclusive nature of the EU trade policy. Discrete national export restrictions were in fact in place during the outbreak of COVID-19. While the

114. Commission Implementing Regulation (EU) 2021/2071 subjecting certain vaccines and active substances used for the manufacture of such vaccines to export surveillance, O.J. 2021, L 421.

115. Art. 6(a) TFEU.

116. Art. 3(1) TFEU.

117. The role of EU Member States therein is not unique. On the role of Member States in the EU Common Commercial Policy see Gappa and Lutz, "The role of Member States in the CCP" in Hahn and Van der Loo (Eds.), *Law and Practice of the Common Commercial Policy: The First 10 Years After the Treaty of Lisbon* (Brill, 2021), p. 531.

Commission could have attempted to challenge their maintenance in force under a proportionality assessment,[118] Article 36 TFEU does allow national protective measures in the domain of health protection. Significantly, moreover, national restrictive measures on exports pursuing the objective of health protection are not prohibited by the EU Regulation on common rules for exports.[119]

EU operational autonomy emerges as a framework where law and politics meet. This holds true also in its external facet. Notwithstanding the seemingly dry details of the exercise of the Commission implementing rules, the political salience of the exercise of EU executive powers is not negligible. Indeed, the comitology examination procedure, governing the domains both of health protection[120] and of trade,[121] reveals the political role of the Commission in the design and amendment of the EU-wide export mechanism. In fact, the political decisions in the amendment of the export regime eventually rest on the Commission, especially in the contested cases where the Member States committees are split or deliver no opinion. This suggests that the exercise of the Commission executive and implementing powers is not a mere technical exercise: it involves political choices.[122] In turn, the passage from export authorization to an export monitoring mechanism after the discussions between Member States, may signal the influence of Member States in the political choices of the Commission. The political nature of the external dimension of EU operational autonomy unfolds even more clearly when considering third country association thereto.

5. Association: Neighbouring countries' participation and exemption regimes

The study of third country association to EU operational autonomy sheds light on how its framework contributed to shaping the EU's international relations in its neighbourhood. Internally, third country association took the form of the extension of Joint Procurement Agreements to privileged partners of the EU. In that regard, Article 165(2) of the EU General Budget Regulation envisages that "joint procurement may be conducted with EFTA States and Union candidate countries".[123] Remarkably, the Joint Procurement Agreement,

118. See *supra* section 2 and particularly note 22 on the Commission's stance.
119. Art. 10 Regulation (EU) 2015/479, cited *supra* note 79.
120. Art. 2(2)b(iii) Regulation (EU) 182/2011, cited *supra* note 80.
121. Ibid., Art. 2(2)b(iv).
122. See further on this Craig, "Comitology" in id., *EU Administrative Law* (OUP, 2018).
123. Regulation (EU) 2018/1046, cited *supra* note 31.

initially undertaken only by some EU Member States,[124] has progressively included all the EU and EFTA members, as well as the UK and a significant number of candidate and potential EU member candidates. The most prominent increase in the signatures of the Joint Procurement Agreement occurred between the end of February and end of April 2020 during the outburst of the COVID-19 pandemic.[125] The joint procurement framework has been used for the supply of drugs to be used to fight the pandemic and has been extended beyond EU membership, especially in the EU's neighbourhood.[126] The possible association of countries of the European Economic Area was expressly envisaged in the amended Regulation on the Emergency Support Instrument, which served as a legal basis for the conclusion of the APAs for vaccines. Here, it was indicated that the EEA States signatories of the Joint Procurement Agreement could take part "in EU-managed procurements of medical countermeasures".[127]

The association of third countries to the internal facet of EU operational autonomy has emerged more distinctively in the EU APAs for vaccines, and particularly in the context of the EU vaccines sharing mechanism. The mechanism has offered a privileged venue with respect to COVAX for channelling EU international cooperation efforts for vaccine purchase and distribution.[128] While substantially investing in the COVAX facility,[129] the EU ultimately decided on separate APAs to secure its vaccine doses, leveraging its market weight and power. The APAs were also conducive to the creation of a vaccine sharing mechanism, not dependent on COVAX, to sell or donate vaccines to its closest partners. The countries targeted through the EU sharing mechanism were mainly those participating in the extended EU internal market and neighbours with closer legal and political ties to the EU.[130]

124. Originally on 20 June 2014, the signatories were Belgium, Croatia, Czechia, Cyprus, Estonia, Greece, Latvia, Malta, Netherlands, Portugal, Serbia, Slovakia, Slovenia, Spain, and the United Kingdom.

125. European Commission, "Signing ceremonies for Joint Procurement Agreement", available at <ec.europa.eu/health/preparedness_response/joint_procurement/jpa_signature_en>.

126. European Commission, "Coronavirus: Commission signs a Joint Procurement Contract with Gilead for the supply of Remdesivir", Press Release, Brussels (8 Oct. 2020).

127. Recital 20 of Council Regulation (EU) 2020/521, cited *supra* note 43.

128. COVAX is the global procurement initiative aimed at granting fair and equitable access for every country in the world, especially low-income countries. COVAX is led by GAVI, the vaccine Alliance, the World Health Organization, the Coalition for Epidemic Preparedness Innovations, and UNICEF.

129. See European Council, "Conclusions on COVID-19", 25 May 2021.

130. COM(2021)35, Commission Communication, "A united front to beat COVID-19", 19 Jan. 2021, p. 10.

This laid the foundations for the progressive development of a Health Union, based on EU membership, but extended to the broader European region. The fabric of the wider European operational autonomy has been sustained by a composite set of relations nurturing an interplay of the internal and external facets of EU operational autonomy, emerging especially in its associative dimension.

Third country association to the internal dimension of EU operational autonomy via the EU APAs has been noteworthy. Specific clauses in the APAs envisage that EU Member States may purchase doses for EEA Members and allow for the possibility to purchase or donate doses to third countries.[131] Pursuant to these clauses, Sweden has facilitated the reselling of vaccines to Norway and Iceland.[132] At a later stage, the same clauses of the EU APAs with pharmaceutical companies were mobilized to secure COVID-19 vaccines for the Western Balkans. In this case, the vaccines were funded by the Commission and shared, with the facilitation of Austria.[133]

Neighbouring country association to EU internal operational autonomy thus brings to the fore the composite external relations dynamics working within the internal facet of EU operational autonomy. Remarkably, moreover, also in its associative articulation, the mixed nature of the EU operational autonomy framework unfolds: association to the distribution of the vaccines purchased at the EU level was enabled primarily by the actions of EU Member States.

Third country association to the external dimension of EU operational autonomy took the form of exemption regimes in the EU export authorization

131. The most specific clause is present in the APA concluded with Moderna which envisages the conditions under which "each Participating Member State shall be entitled to re-sell, export and/or distribute the Product doses . . . to other EU or EEA Member States". See European Commission, Advance Purchase Agreement for the production, priority-purchasing options and supply of successful COVID-19 vaccine for EU Member States [with Moderna], I.4.6, pp. 12–13. Moreover, the APA concluded with AstraZeneca contemplated the possibility "to donate or resell, at no profit [vaccine] doses to other European Countries that agree to be bound by the terms and the conditions of this Agreement applicable to a Participating Member State", European Commission, Advance Purchase Agreement for the production, purchase and supply of a COVID-19 vaccine in the European Union [with AstraZeneca], Ares(2020)4440071, 26 Aug. 2020, Art. 8.3(b-c), p.17. The APA with Pfizer BioNTech also envisaged the possibility for the Product granted by the European Commission "to be placed on the market in the European Economic Area". Besides, a more flexible clause reads that "[a]ny vaccines available for purchase under the APAs . . . can be made available to the global solidarity effort". See European Commission, Advance Purchase Agreement for the development, production, priority-purchasing and supply of successful COVID-19 vaccine for EU Member States [with Pfizer BioNTech], Sante/2020/C3/043-SI2.838335.

132. Garza, "The Swedish Government will secure Norway with Covid-19 vaccines", *Norway Today* (26 Aug. 2020).

133. European Commission, "The European Commission and Austria secure COVID-19 vaccines for the Western Balkans", Press Release, Brussels (20 April 2021).

mechanism. Although the original Commission Implementing Regulation on PPE did not envisage derogations, the mechanism was swiftly amended to exclude from its scope of application the EFTA States and the European microstates.[134] The justification for the exemption read that "the single market for medical and personal protective equipment is closely integrated beyond the boundaries of the Union . . . This is particularly the case of the four Member States of the European Free Trade Association". The inclusion of these States in the export authorization mechanism would be thus "counterproductive, given the close integration of the production value chains and distribution networks".[135]

Similar rationales informed the exemption regimes of the vaccine export authorization mechanisms. The original Commission Implementing Regulation envisaged a broad spectrum of exemptions, including the Western Balkan countries and the other European neighbours participating in the EU's proximity policies.[136] The Commission justified the exemptions on the basis that EFTA members and the Western Balkans are "engaged in a process of deep integration with the Union".[137] Exemptions have also been envisaged for the low income countries benefiting from the COVAX global solidarity effort**.** The EU export authorization scheme and its exemption regimes have thus been embedded in the EU trade policy characterized by closer trade and political links in the closer neighbourhood and development cooperation initiatives in the wider world.

The text of the Implementing Regulations pointed out that the exemptions were justified by the fact that the "single market for medicinal products is closely integrated beyond the boundaries of the Union, and so are its supply chains and distribution networks".[138] In the more acute phases of the crisis, the geographical scope of the exemption was progressively restricted. It was noted that "the information collected by the Commission through the export authorization mechanism . . . has shown that exports which are subject to the authorization mechanism may be channelled via countries so far exempted from the export authorization requirement, thereby not allowing for the

134. In addition to the territories listed in Annex II TFEU, and Andorra, Monaco and San Marino, the exemption included two other micro territorial entities, Vatican City and the Faroe Islands. Both are strictly connected with EU Member States (Italy and Denmark respectively).

135. Recital 2 Commission Implementing Regulation (EU) 2020/426 of 19 March 2020 amending Implementing Regulation (EU) 2020/402 making the exportation of certain products subject to the production of an export authorization, O.J. 2020, L 84I.

136. Art. 1(5), Implementing Regulation (EU) 2021/111, cited *supra* note 84.

137. Ibid., Recital 11.

138. Ibid.

required level of transparency".[139] Most of the exemptions were thus suspended.[140]

The suspension met with the hostility of the EEA EFTA States, which made a request to "rectify the export authorization scheme" finding it "incompatible with the EEA Agreement".[141] The EU had explained that the new Implementing Regulation would not affect relations with the EFTA States, as vaccines for them had been "secured through the [EU] Advanced Purchase Agreement".[142] This was clarified in the subsequent Commission Implementing Regulation (EU) 2021/734 of 5 May 2021.[143] Here, it could be read that:

> "Iceland, Liechtenstein and Norway . . . participate in the Union's internal market in accordance with the [EEA Agreement]. Most exports to the States consist of vaccines procured by a Member State pursuant to an Advance Purchase Agreement concluded by the Union and resold to those countries".

In the Commission's view, an express indication of the exemption for EEA EFTA States would be redundant: their association to the internal facet of the EU operational autonomy framework would naturally result in their association to the external dimension via the exemption regimes. In the subsequent amendment, the EEA exemption was expressly flagged: it was observed that in "application of Implementing Regulation (EU) 2021/521 there is no indication that exports are being channelled through the EEA EFTA States to other countries not exempted from the export authorization mechanism".[144] Again, this signals a complex set of relations in the wider European legal space emerging in the interplay of internal and external aspects in neighbouring country association to EU operational autonomy.

Third country association to EU operational autonomy illustrates how it can be hard to disentangle the legal from the political. The exemption regimes of the implementing regulations may be construed as a reflection of the different political covenants underpinning the EU's neighbourhood relations law. The Union membership political covenant has reconfigured both the

139. Recital 5 of Commission Implementing Regulation (EU) 2021/521, cited *supra* note 95.

140. Ibid., Recital 6. (Andorra, the Faroe Islands, San Marino, Vatican City, the overseas countries and territories listed in Annex II TFEU, Büsingen, Helgoland, Livigno, Ceuta and Melilla). The exemption thus included territories which are not formally part of the EU Customs Union.

141. EEA, 55th Joint European Economic Area Parliamentary Committee, 28 April 2021.

142. Ibid.

143. Commission Implementing Regulation (EU) 2021/734, cited *supra* note 99.

144. Ibid., Recital 6.

paradigms of sovereignty exercise within the Union,[145] and the terms of reference for the protection of public interests. It nurtured an essential set of relations between the EU institutions and the Member States and among the Member States themselves.[146] Although different from the EU membership covenant, the covenants underlying the arrangements of EU neighbourhood law mirror and shape the intensity of the association between the EU and its partners, and the ensuing legal and political relations.[147] In that light, the fact that political contexts inform the legal arrangements, as in the vaccine export authorization mechanism, does not mean that such a mechanism is arbitrary.[148] On the contrary, law plays a defining role in shaping the context of these political relations.

The EU's constitutional mandate to develop special relationships with neighbouring countries is enshrined in Article 8 TEU. The intensity of gravitation around the EU's legal order varies in function of the legal arrangements between the EU and its neighbouring countries and the underlying political covenants. With regard to the EEA, in *Ospelt*, the ECJ recognized that "one of the principal aims of the EEA Agreement is to provide for the fullest possible realization of the free movement of goods, persons, services and capital within the whole European Economic Area, so that the internal market established within the European Union is extended to the EFTA States".[149] The closeness of the EEA regime to EU membership law derives from the intensity and scope of the EEA Agreement and its developed enforcement mechanisms.[150] The absence of these mechanisms in EU-Swiss relations may explain the different treatment of Switzerland from the other EFTA Members in the patterns of association to the EU operational autonomy framework.

The shifting and reduced scope of geographical exemption, mainly privileging the EEA EFTA partners in times where shortages of critical substance and vaccines were more alarming, signals a gradation in the intensity of neighbouring country association to the EU framework. Indeed, varying foreign policy relations are in place between the EU and its neighbouring countries. Crucially, these different foreign policy stances are

145. See famously Case 26/62, *Van Gend & Loos* v. *Netherlands Inland Revenue Administration*, EU:C:1963:1.

146. Opinion 2/13, *EU Accession to the ECHR*, EU:C:2014:2454, para 167.

147. See Petti, *Wider Europe: The Extension of the EU's Legal Space,* PhD thesis, Sciences Po Paris, 2021.

148. The question on the arbitrariness of the EU COVID-19 vaccines export mechanism was raised, *inter alia*, in Evenett, "Export controls on COVID-19 vaccines: Has the EU opened Pandora's box?", 55 JWT (2021), 397, at 401.

149. Case C-452/01*, Ospelt*, EU:C:2003:493, para 29.

150. See e.g. Arts. 6, 105, 106, 111(3) Agreement on the European Economic Area (EEA), O.J. 1994, L 1.

both a reflection and a product of the law. The different echelons of legal intensity characterizing the EU's proximity policies have been indirectly acknowledged in a set of ECJ rulings on the extension of the EU Regulation on social security systems.[151] These were in the context of bilateral and multilateral international agreements concluded between the EU and neighbouring countries.

Elements of the varying degrees of third country association to the EU can be seen in the seemingly legalistic choice of the substantive legal bases for the relevant Council decisions intending to extend the social security Regulation to the international agreements governing the EU's neighbourhood relations. The ECJ acknowledged that the legal basis for the Council decisions concerning the international agreements with the EFTA States should be adopted with the same substantive legal basis as the originating EU Regulation (Art. 48 TFEU).[152] The Council decisions concerning other countries should be based instead on an "external" immigration legal basis (Art. 79(2)b TFEU),[153] with the exception of Turkey for which a dual (association under Art. 217 TFEU and internal market under Art. 48 TFEU) substantive legal basis was needed.[154] In the case of the extension of the EU Regulation to the EEA, the Court maintained that "the contested decision is . . . precisely one of the measures by which the law governing the EU internal market is to be extended as far as possible to the EEA, with the result that nationals of the EEA States concerned benefit from the free movement of persons under the same social conditions as EU citizens".[155] In the case of Switzerland, the Court did not reiterate the reasoning on the extension of the internal market. In a narrower fashion, it referred to the extension of the specific pieces of EU legislation to Switzerland to justify the appropriateness of Article 48 TFEU as the substantive legal basis for the contested decision in the context of EU-Swiss legal relations on free movement of persons.[156]

The far-reaching political covenant underlying the EEA Agreement and the ensuing privileged legal relations have been confirmed more recently in *Ruska*

151. Regulation (EC) 883/2004 of the European Parliament and of the Council on the coordination of social security systems, O.J. 2004, L 166.

152. For the EEA see Case C-431/11, *United Kingdom* v. *Council*, EU:C:2013:589, paras. 50–61; for Switzerland Case C-656/11*, United Kingdom* v. *Council*, EU:C:2014:97, para 64.

153. See further on this, Dashwood, "EU Acts and Member State Acts in the negotiation, conclusion, and implementation of international agreements" in Cremona and Kilpatrick (Eds.), *EU Legal Acts: Challenges and Transformations* (OUP, 2018), p. 239. See also Bekkedal, "The application of EU internal competences in an external context: UK v Council (EEA)" in Butler and Wessel (Eds.), *EU External Relations Law: The Cases in Context* (Hart Publishing, 2022), p. 701.

154. Case C-81/13*, United Kingdom* v. *Council*, EU:C:2014:2449.

155. Case C-431/11, *United Kingdom* v. *Council*, para 59.

156. Case C-656/11, *United Kingdom* v. Council, EU:C:2014:97, paras. 62–64.

Federacija.[157] The ECJ held that, even in the politically sensitive domain of extradition, the citizens of Iceland (and Norway) find themselves in a situation that is "objectively comparable with that of EU citizen to whom . . . the European Union offers an area of freedom, security and justice without internal frontiers".[158] In addition to the disentanglement of Brexit from the EU and the rather distant new EU-UK association,[159] also the EU-Swiss relations have been experiencing some strain. Difficulties emerged particularly after the Swiss reluctance to conclude an Institutional Framework Arrangement with the EU. This arrangement would have allowed a greater homogeneity in interpretation and enforcement of EU law extended to Switzerland[160] to reduce the gap with the mechanisms envisaged by the EEA homogeneous legal space.[161]

Hence, the motives underlying the exemption regimes can be found in the different types of legal associations contemplated by EU neighbourhood law. These are additional to the dependence of European microstates and territories on the metropolitan supply chains of the Member States to which they are attached or on the supply chains of neighbouring Member States.[162] These different legal relations are justified by the fact that, contrary to what happens within EU membership, the EU is not bound to apply the principle of equal treatment to third countries.[163] Different levels of intensity in EU foreign relations are thus allowed under EU law[164] and shaped through EU neighbourhood law.

The patterns of neighbouring country association to the EU operational autonomy framework have been confirmed in the more recent measures of EU operational autonomy, namely in the context of the REPowerEU Plan and EU4Health programme. In the former case, the relevant Commission Communication clarifies that the proposed EU energy platform for the

157. Case C-897/19 PPU*, IN* v. *Ruska Federacija*, EU:C:2020:262, paras. 44 and 50.

158. Ibid., para 75.

159. See EU-UK Trade and Cooperation Agreement, O.J. 2021, L 149.

160. Arts. 4(2) and 10(3) EU-Switzerland Draft Institutional Agreement, *Accord Facilitant Les Relations Bilatérales Entre l'Union Européenne et La Confédération Suisse Dans Les Parties Du Marché Intérieur Auxquelles La Suisse Participe* (Institutional Agreement – Draft Text), 23 Nov. 2018, available <www.eda.admin.ch/dam/europa/fr/documents/abkommen/Acccord-inst-Projet-de-texte_fr.pdf>.

161. See *supra* note 150.

162. Recital 6 Commission Implementing Regulation (EU) 2021/521, cited *supra* note 95.

163. Case C-272/15*, Swiss International Air Lines AG* v. *The Secretary of State for Energy*, EU:C:2016:993, paras. 23–29. See also Case 55-75*, Balkan-Import Export GmbH* v. *Hauptzollamt Berlin-Packho*, EU:C:1976:8, para 14; Case 52/81*, Werner Faust* v. *Commission,* EU:C:1982:369, para 25; Case C-122/95*, Germany* v. *Council*, EU:C:1998:94, para 56; Joined Cases C-364 & 365/95*, T Port* v. *Hauptzollamt Hamburg-Jonas*, EU:C:1998:95, para 76.

164. For more on this see Pedreschi and Scott, "External differentiated integration: Legal feasibility and constitutional acceptability", EUI RCAS, Paper No. 2020/54.

common purchase of gas is open for the "EU's partners in its close neighbourhood, partners who are committed to the EU's internal market rules and joint security of supply."[165] In turn, the Regulation establishing the EU4Health Programme features provisions dedicated to third countries associated to the programme with a focus on the closest neighbours.[166] Norway and Iceland have participated alongside the EU Member States in the context of the Union's response to the monkeypox outbreak.[167] By harnessing the political weight and market power of this wider European legal space, the effectiveness of the EU's actions is increased while cementing solidarity at the broader European level. Third country association to EU operational autonomy reflects how EU law manages and fosters interdependences beyond membership, while pursuing its strategic objectives.

6. EU operational autonomy: The tension between multilateral and regional commitments

Vaccine diplomacy has been a ground for geopolitical competition in the global arena. While it has been noticed how China and Russia have regarded "the vaccine crisis as an opportunity to advance geopolitical goals" by cementing "existing ties or develop[ing] new alliances",[168] the successfulness of these endeavours remains largely disputed.[169] In turn, the development of the EU's international relation strategy on vaccines has proved rather slow, with the EU initially focused on the setbacks of its own early struggles in the vaccination campaign.[170]

While involved in the COVAX facility, the EU preferred its own vaccine sharing mechanism for procuring doses for its Member States and its neighbouring partners.[171] Both the EU's participation in the COVAX facility and the EU's own vaccine sharing mechanism have been characterized by a similar format. Indeed, the joint participation of the EU and its Member States

165. COM(2022)230, cited *supra* note 68, p. 5.

166. Art. 6 Regulation (EU) 2021/522, cited *supra* note 63.

167. European Commission, Press Release, cited *supra* note 64.

168. Gruszczynski and Wu, "Between the high ideals and reality: Managing COVID-19 vaccine nationalism", 12 EJRR (2021), 711, at 719.

169. Bremmer, "Why the Chinese and Russian vaccines haven't been the geopolitical wins they were hoping for", *Time* (2 Aug. 2021).

170. Wheaton and Deutsch, "Europe prepares late entry in vaccine diplomacy race", *POLITICO* (6 May 2021).

171. European Commission, "Statement by Commissioner Kyriakides to the Plenary of the European Parliament on the EU's global strategy on COVID-19 vaccination" (19 Jan. 2021).

has been centred on the "Team Europe" format, also including EEA EFTA States,[172] with the intent to "muster a critical mass that few others can match".[173] Yet, the choice for giving preference to the EU's own vaccine mechanism was due to the fact that this was considered better suited for allowing the EU to pursue its international strategic priorities with greater visibility and a more marked regional targeting,[174] centred on the Western Balkans[175] and the privileged partners in the EU's neighbourhood.[176]

The EU vaccine strategy has thus been criticized for contributing to a disturbing vaccine nationalism.[177] While the COVAX global procurement effort has not met the ambitious expectations that inspired its launch,[178] the rather dismal results have also been due to the decisions of major public powers, such as the EU, to prioritize their own purchase programmes.[179] Against this backdrop, a question arises as to how the EU operational autonomy framework relates to and complies with the EU's multilateral commitments.[180] The balancing of regional and multilateral commitments has not only a political, but also a constitutional tenor. Alongside the constitutional mandate to establish privileged relations in the neighbourhood (Art. 8 TEU), the EU is bound to promote multilateral solutions to common problems (Art. 21 TEU).

172. Indeed, the Team Europe joined the COVAX facility as the European Commission acting on behalf of the EU Member States plus Norway and Iceland. See WHO, COVAX, Commitment agreements to the COVAX Facility, 15 Dec. 2020, p. 3, available at <www.who.int/publications/m/item/list-of-participating-economies>.

173. Ibid., especially the European Investment Bank (EIB) and the European Bank for Reconstruction and Development (EBRD).

174. Chadwick and Lei Ravelo, "Inside the European Commission's global vaccine-sharing plan", *Devex* (18 Feb. 2021).

175. Especially after some EU Member States invited the Union "to take a strategic look at the Western Balkans". Brzozowski and Makszimov, "Bring Western Balkans back on the agenda, urge nine EU Member States", *EurActiv* (11 March 2021). This was a response to raising geopolitical rivalries and shortcomings connected to vaccines in the Western Balkans. See Juncos, "Vaccine geopolitics and the EU's ailing credibility in the Western Balkans", *Carnegie Europe* (8 July 2021).

176. European Commission and EU High Representative, "Communication on the Global EU response to COVID-19", of 8 April 2020, JOIN(2020)11 final; see also COM(2021)35, cited *supra* note 130.

177. von Bogdandy and Villareal, "The EU's and UK's self-defeating vaccine nationalism", *Verfassungsblog* (26 Jan. 2021); Marceau and Parwani, "COVID-19 and international trade: The role of the WTO in fighting the pandemic and building back better", 16 *Global Trade and Customs Journal* (2021), 281.

178. Usher, "A beautiful idea: How COVAX has fallen short", 397 *The Lancet* (2021), 2322.

179. For a broader discussion, see Zhou, "Vaccine nationalism: Contested relationships between COVID-19 and globalization", *Globalizations* (2021), 1.

180. See especially Art. 21(1) TEU.

It can safely be maintained that relying on the COVAX alone would have laid the foundations for a more equitable response to the pandemic at the global level. Nevertheless, the EU operational autonomy framework and its related sharing mechanism enabled the Union to attain its vaccination objectives and to substantiate its region-building commitments with regard to its proximity policies.[181] The operation of the EU's own vaccine mechanism in parallel to COVAX signals a balancing between multilateral and regional commitments. This balancing emerges particularly when examining neighbouring country association to EU operational autonomy via the exemption regimes of the export authorization mechanism. Indeed, the complexity and gradations of EU neighbourhood law may not entirely fall within the specific categories of multilateral trade regimes.

The EU notified its export authorization mechanisms to the WTO Market Access Committee under Article XX(b).[182] Article XX GATT had influenced the drafting of Article 36 TFEU. Article XX(b) GATT allows national measures "necessary to protect human, animal or plant life or health" provided that they do not constitute an "arbitrary or unjustifiable discrimination between countries where the same conditions prevail". In this respect, legitimacy issues arise with the exemption regimes of the export authorization mechanism. In fact, this complex patchwork of differentiated legal relations of the EU with neighbouring countries is not readily identifiable under GATT law.

Regional trade agreements are generally permitted in GATT law within the limits of Article XXIV GATT. Yet, the GATT does not explicitly address more articulated forms of regional arrangements like common markets or economic unions.[183] Therefore the GATT's categories of Free Trade Area and

181. Hillion, "Anatomy of EU norm export towards the neighbourhood: The impact of Article 8 TEU" in Elsuwege and Petrov (Eds.), *Legislative Approximation and Application of EU Law in the Eastern Neighbourhood of the European Union: Towards a Common Regulatory Space?* (Routledge, 2014).

182. See e.g. WTO, Committee on Market Access, "Notification pursuant to the Decision of Notification Procedures for Quantitative Restrictions (G/L/59/REV.1)" by the European Union of 7 May 2020 (20-3481). This notification was on the export control mechanism of PPE; the WTO Justification and Ground for Restriction was "Protection of human life or health, *inter alia*". Similar grounds for justification have been used for the vaccine export authorization mechanism. See WTO, Committee on Market Access, "Notification pursuant to the Decision of Notification Procedures for Quantitative Restrictions (G/L/59/REV.1)" by the European Union of 11 May 2021 (21-4030). The EU could have chosen GATT provisions more deferential to its autonomy as the "carve out" of Art. XI:2(a) GATT or the security exception of Art. XXI GATT. For a discussion, see Pauwelyn, "Export restrictions in times of pandemic: Options and limits under international trade agreements", 54 JWT (2020), 727.

183. Tevini, "Article XXIV. Territorial application – frontier traffic – customs unions and free-trade areas" in Wolfrum, Stoll and Hestermeyer (Eds.), *WTO – Trade in Goods* (Brill/Nijhoff, 2010), p. 625.

Customs Union alone[184] are not entirely exhaustive for evaluating the variety of institutional arrangements of EU neighbourhood law.[185] The extension of the EU internal market through the EEA is a case in point: the EEA has not even been notified under Article XXIV GATT.[186] The EEA may be considered as a preferential trade area, a category which is regarded as a second-best when compared to the trading arrangements expressly contemplated by the GATT, as it is liable to trigger a tension between regionalism and multilateralism.[187]

In spite of the inadequacy of the GATT regime to account for all the arrangements of EU neighbourhood law, two interlinked elements help to elucidate the delicate relations between the EU COVID-19 vaccine mechanisms and relevant regional exemptions on the one hand, and the GATT provisions on the other. First, the density of the relations channelled by EU neighbourhood law affects the "conditions" within the meaning of Article XX GATT: the legal relations between the EU and EEA EFTA States differ from those between the EU and other third countries to such an extent that the conditions are different. EEA EFTA States have decided to join the extended EU internal market and this creates a rather unique set of legal and political relations. Second, and relatedly, the exemption regime granted to EEA EFTA States constitute the external facet of the EEA EFTA States' participation in the *internal* dimension of EU operational autonomy.[188] Both these aspects reinforce the understanding of the EEA as a wider European domestic market. In that light, remarkably, the Union has de facto upscaled health protection as a public interest protected by Article XX(b) GATT, to the territory and the

184. Art. XXIV(4) GATT.

185. Interestingly, differing echelons of integration had been outlined by the then EEC in 1987 during the Working Party on the Accession of Portugal and Spain to the EEC on the relationship between Art. XX(d) and Art. XXIV GATT. The EEC affirmed that preferential treatment of certain products was consistent with the GATT by virtue of Art. XXIV, which permits customs unions to be formed "in accordance with the needs of the integration process they plan to carry out". But at the time, the issue was of preferential treatment between EEC members, not yet in the EU regional partnerships, such as the EEA. This EEC's stance on the relationship between Article XX(d) and Article XXIV GATT mentioned above can be found in WTO Analytical Index, GATT 1994, 6 Oct. 2021, "Relationship between Article XX and other Articles of the General Agreement", 596, available through <www.wto.org/english/res_e/booksp_e/gatt_ai_e/art20_e.pdf>.

186. While it has been notified under Art. V GATT. Previously concluded bilateral FTAs under Art. XXIV GATT are in place between the European Economic Community (EEC) and the EFTA members notified under Art. XXIV GATT.

187. Hilpold, "Regional integration according to Article XXIV GATT – Between law and politics", 7 *Max Planck Yearbook of United Nations Law* (2003), 219. See also Winters, "Preferential trading agreements: Friend or foe?" in Bagwell and Mavroidis (Eds.), *Preferential Trade Agreements: A Law and Economics Analysis* (Cambridge University Press, 2011).

188. Recital 20 of the amended ESI Regulation, cited *supra* note 43.

population of the European Economic Area as a whole, beyond Union membership.[189]

In the delicate balance between the EU's regional and multilateral commitments, EU operational autonomy certainly rests on a rather EU-centric conception of managing interdependences, one which favours the EU's own and regional "European" interests over multilateral ones.[190] Yet it also signals the EU's openness in extending its operational autonomy and solidarity to its closest neighbours sharing common values and a European identity.[191] Moreover, the composite frameworks of neighbouring country association to EU operational autonomy played a part in internalizing externalities, thus enhancing the EU's legitimacy and effectiveness in the broader European legal space. As the recent cases of the EU4Health and REPowerEU programmes demonstrate, the EU's openness and its attitude of internalizing externalities has not been accidental; it is entrenched in the legal structures of EU neighbourhood law. In this sense, EU neighbourhood law can be intended as contributing to regional developments of international law.

While already operative at the regional level, the alleged openness of the EU strategic autonomy risks remaining declaratory in the broader multilateral arena. In the EU's institutional discourse, "open strategic autonomy" is qualified as "the EU's ability to make its own choices and shape the world around it through leadership and engagement, reflecting its strategic interests and values".[192] In fact, as the vaccines case shows, the EU's openness to third country association to the legal frameworks pursuing EU autonomy seems to occur mainly with countries participating in the extended EU's legal space and sharing with the EU common values, interests, and a European identity. The challenge is thus to fulfil the EU's constitutional mandate to promote multilateralism with countries that have less in common with the EU, by devising legal and policy frameworks that are not necessarily premised on the extension of the EU's legal space, as is the case with EU neighbourhood law.

The legal frameworks examined in this article have shown how legal principles upheld by the EU, such as solidarity,[193] may be differently operationalized. The parallel functioning of the EU's own vaccine purchase

189. Instead, the opportunity to scale up the understanding of Art. XX GATT exceptions as protecting the interests of the WTO as a whole in light of the WTO preamble has been missed in WTO, Appellate Body Reports, China – Raw Materials, WT/DS394/AB/R, WT/DS395/AB/R, WT/DS398/AB/R, 30 Jan. 2012. See also Espa, "The appellate body approach to the applicability of Article XX GATT in the light of China – raw materials: A missed opportunity?", 46 JWT (2012), 1399, at 1420.

190. Editorial Comments, op. cit. *supra* note 3, at 321.

191. See both Art. 8 TEU and Recital 2 of the EEA Agreement, cited *supra* note 150.

192. COM(2021)66 final, cited *supra* note 52, p. 4.

193. Art. 21 TEU.

and distribution mechanism for Union members and the EU's closest partners alongside the COVAX facility is an example of this. The different operationalization reflects the EU's varying strategic priorities in its external partnerships and legal alliances. Foreign relations are inherently based on differentiated partnerships: the factual contexts and policy priorities, ensuing also from the varying density of legal relations, are not the same for all the EU's partners.

Although accepted among the EU's closest European neighbours, the EU-centrism of the legal frameworks does not seem credible nor tenable for the attainment of the European Union's objective of a truly "open strategic autonomy" globally.[194] The EU's discourse on "open strategic autonomy" risks engendering confusion regarding the relationship between EU values and interests, which, in EU policy documents, are often intended as coterminous.[195] This approach raises questions as to the extent to which the EU institutional actors assume not only the existence of truly shared values and interests among EU Member States,[196] but also that the Union can "shape the world" around "its ability to make its own choices" while reflecting its interests and values.[197] In fact, as acknowledged by the EU, the engagement of the "West" in the international community is increasingly questioned, as it reflects values that may be not necessarily regarded as universal.[198]

The EU constitutional mandate prescribes that the Union's external action is to be guided by the principles which have inspired its own creation,[199] and in its relations with the wider world, the Union "shall uphold and promote its values and interests".[200] The EU's foreign policy action would benefit from a more discernible articulation of the links and possible frictions between its multiple foreign policy drivers. In particular, greater clarity would be welcomed in identifying how values, principles, and interests may be differently tempered, balanced, or even reconciled, in different contexts. The vaccine mechanism case has shown how political contexts deeply inform the EU's legal frameworks. This intertwining of law and politics has resulted in a different balancing and ranking of the EU's interests and strategic priorities

194. Commission Joint Research Centre (JRC) Science for Policy Report, "Shaping and securing the EU's open strategic autonomy by 2040 and beyond" (2021), available at <publications.jrc.ec.europa.eu/repository/handle/JRC125994>.

195. European Union, "Shared vision, common action: A stronger Europe: A global strategy for the European Union's foreign and security policy", 28 June 2016, pp. 13–14. See also Commission Communication cited *supra* note 52, p. 6.

196. Editorial Comments, "'*We perfectly know what to work for*': The EU's global strategy for foreign and security policy", 53 CML Rev. (2016), 1999, at 1201.

197. COM(2021)66 final, cited *supra* note 52.

198. Science for Policy Report, cited *supra* note 194, p. 21.

199. Art. 21(1) TEU.

200. Art. 3(5) TEU.

and principles, between the regional and global level. Engagement in multilateralism on the part of the EU may require not only greater awareness of the complex relations between the EU's foreign policy drivers, but also a vision as to how to reconcile its own interests and values with those of countries with different values and priorities and how to reflect this reconciliation in the development of multilateral rules.

7. Concluding remarks

The study of the EU's executive actions in the procurement and export regulation of critical goods and vaccines has constituted a fruitful laboratory for assessing the interface between law and politics in the pursuit of European strategic objectives. By examining the actions of the EU's executive, the notion of EU operational autonomy has been introduced to capture the way in which the EU legal framework channels the EU's policy objectives and strategic priorities.

The EU operational autonomy framework related to the EU's COVID-19 purchase and export mechanisms has been examined in its internal and external facets. Internally, EU operational autonomy materialized in the development of a unitary framework for the procurement and advance purchase of critical resources and vaccines. Externally, it resulted in the implementation of an EU-wide export scheme. The EU operational autonomy framework thus cuts across Union competences. It ranges from the supportive competences pertaining to health protection to the exclusive competences of EU trade policy.

Significantly, EU operational autonomy appears to herald a shift in internal market rationales pointing towards a more active role and intervention of public powers in the market. This has emerged both in the centralization of purchase and distribution of critical resources and in EU-wide export regulations. The interventionist exercise of public powers aims at harnessing the collective political weight and market leverage of the Union and its Member States with a view to ensuring fair distribution and solidarity among EU States and peoples. In this understanding, unity as a characteristic of the legal framework is hardly severable from unity as a policy choice. Indeed, while fragmented national measures might have been legally possible, they would have posed existential threats to the Union; they would have undermined the political and legal viability of the internal market, reducing its global leverage for the pursuit of its strategic objectives.

The intertwining of law and politics is particularly evident in neighbouring country association to EU operational autonomy. The EEA EFTA States' close

involvement in EU operational autonomy, in particular, cannot be fully understood without considering the political covenants underlying the arrangements of EU neighbourhood law providing for the extension of the EU internal market. Through neighbouring country association to EU operational autonomy, the Union manages interdependences in a wider European legal space. In this way, the EU harnesses this wider political weight and market power in pursuit of European regional objectives and priorities. Significantly, moreover, the shaping of EU neighbourhood relations also changes the terms of reference for the interests to be protected in the exercise of public powers. By scaling up the strategic public objective of health protection to the EEA as a whole (including to a different degree also the Western Balkans), the EU has internalized externalities in a wider European area. It has engendered a legal and political framework fostering regional solidarity beyond EU membership.

Neighbouring country association to EU operational autonomy has also disclosed the composite external relations dynamics within the internal facet of EU operational autonomy, with some Member States promoting the association of their closest regional partners. The analysis of the associative framework has also brought to the fore a possible tension between the Union's regional and multilateral commitments. The article has shown how the differentiated legal international relations established by the EU, with privileged relations in its neighbourhood, may be considered compliant with multilateral trade rules, although current multilateral rules do not entirely capture the complexity and gradations of the EU's regional partnerships.

The study of EU operational autonomy in the EU COVID-19 vaccine mechanism has illustrated the consolidation of two principal trends that may be conducive to paradigmatic shifts in EU law. One is executive centralization at the EU level and a more interventionist exercise of public powers in the regulation of the market. The other is the EU's predilection for European regional endeavours and interests over multilateral ones, in the context of the mounting quest for autonomy on the part of the EU also in other domains characterized by scarcity of resources. The effects of executive centralization on the nature and equilibria of Union law appear tempered by the mixed governance and implementation framework envisaging significant roles for EU Member States. More pressing constitutional, political, and ethical challenges arise with regard to the balance between the EU's regional and multilateral commitments in the pursuit of European strategic objectives and autonomy.

The challenge lies in fulfilling the EU's constitutional mandate to promote multilateralism by devising legal and policy frameworks that are not necessarily premised on the extension of the EU's legal space, as is the case in EU neighbourhood law. A thorough awareness and identification of the

possible frictions that the growing quest for European strategic autonomy could trigger in the interplay between EU values and interests at the global level would be beneficial. The vaccine case has illustrated how the EU has ordered strategic priorities differently at the regional and global level, modulating the application of the legal principle of solidarity through distinct legal frameworks at the regional and global level. In this respect, greater clarity on the different balancing of EU values and interests would also require a genuine engagement of the Union with the diverging interests and values of its global partners. Difficult as it may seem in times of growing geopolitical rivalries, this would consolidate the EU's leadership in the establishment of an open multilateral system by fostering a broader ownership of multilateral rules.