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Health services after COVID-19 emergency: toward a multilevel system?

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Sommario

Abstract

The paper aims to analyze how the administrative organization has affected the retention of the guarantee levels of social rights (i.e., health, education and local social services) following the impact of coronavirus on the various systems. In particular, the analysis aims to understand how the organizational structures deriving from different balances (public/private; center/periphery; entity of the cost/minimum levels of services; quality "excellence" in the service/quantitative enlargement of the service) have impacted on some section of the population, affecting freedoms in general. The analysis will draw useful information for the post-emergency which must be based on a new interpretation of the principles of efficiency and effectiveness to understand the space of social and territorial cohesion in the reorganization of services and to make this reorganization structurally efficient in relation to rights and freedoms.

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1. *Introduction.*

In the last decades, both the idea and the management of public services have been the object of a relevant evolution in all the EU Member States, searching for the right balance between the necessity to answer to the citizens' needs offering them high quality and low-cost performances and the exigency to reduce the wastes and over-costs generated by an organization scarcely oriented to a managerial perspective and often permeated by political interest.

Due to its strict interconnection with fundamental rights and with issues related to public order and community well-being, public health is a significant example of the reform process of public services. Particularly in Italy, in the last three decades, several normative interventions have been adopted aimed to increase service effectiveness and efficiency while safeguarding the universal and accessible nature that is the distinctive character of the Italian Public Health Service. After the reform of Title V, Part II of Constitution (Const.), Regions acquired relevant competencies and autonomy in the organization of health services, with the effect of a progressive differentiation (and fragmentation) of the organization and management models, only partially reduced by the Central Government interventions aimed to assure service uniformity and coherence on the whole national territory.

Nevertheless, starting from the 2007 economic crisis, budget austerity and reduction of sovereign debt caused significant cutting in the public health investments and stimulated the involvement of private operators in providing a health service, with costs growing for citizens and weakening of the controls on quality.

The Covid-19 emergency outbreak showed all the limits of the austerity, fragmentation, and the necessity to better define the private operators' role and margin of manoeuvre. At the same time, it put in evidence the necessity of rethinking the role of the European Union (EU) in the health sector, limited until now essentially to complete the Member States' action.

During the sanitary emergency, the EU played a relevant role not only in providing financial funds, but also in assuming a coordination role in the supply of medical devices, medicines, and vaccines. To assure concrete support to the Member States, exhausted by the pressure on the domestic health systems and the economic crisis determined by the prolonged lockdown, it resorted to instruments such as joint procurement, able to overcome the differences between the national administrative systems and procedures to assure effectiveness, equity, accessibility, and continuity in the supply of the goods necessary to face the pandemic.

The present contribution aims to assess, in a multidisciplinary perspective, the concrete effectiveness of service provision multilevel models, taking as a case study the Italian health service. Analyzing the process of decentralization, managerialization, and privatization of the Italian System, the study first highlights the system's strengths and limits and the lacks and critical issues encountered by the

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Italian Health System in facing the emergency. Secondly, the analysis focuses on the instruments elaborated by the EU to overcome the differentiation and limits of the national health system, verifying the effectiveness of the joint procurement procedures in assuring availability and accessibility to medical goods.

Part I
The Italian public health system put to the test by the Covid-19 emergency: present problems and future perspectives

I.1 Actors and competences in health sector management: an introduction
Public health organization aims to satisfy and protect the individual rights of the public service users. For a long time, it has been the object of an institutional debate concerning the future of the Italian Health Service (SSN) and the reforms which are necessary to its survival.
Recently, it acquired new lifeblood from the reform project of Title V, II Part, Const., aiming to redefine the competence framework between Central Government and the Regions in the sector of 'Health protection' and 'Health Governance' delineated by Constitutional Law n. 3/2001[1] and not fully defined yet.
Indeed, there are several problems concerning the concrete application of Article 32 Const. protecting the right to health as a fundamental individual right and collective interest. These problems come from the overlapping of 'health protection' competence attributed to the Regions by Art. 117, §3, Const., and the competences attributed to the Central Government by Art. 117, § 2, Const.
As a consequence, the centralization at the national level of legislation and execution is a source of conflicts in sectors as, for example, health assistance, the establishment of service essential levels concerning civil, and social rights to be assured on the whole national territory. Conflicts arise also in the sectors where the Central Government limits itself to establish rules and essential criteria which Regions have to respect in the organization of Regional Sanitary Systems (SSR) and the adoption of detailed legislation to assure service uniformity on the whole national territory.
For a long time, the relationship between the Central Government and the Regions has been rather strained due to the difficulty to conciliate expense saving, health

* Mariaconcetta D'Arienzo edited Part I, Sara Pugliese edited Part II. Introduction and Conclusions are the result of common reflections.

[1] On the framework of the competence relationship among Central Government, Regions, and local authorities in the public health sector after Constitutional Law 3/2001, see *La riforma del rapporto Regione-istituzioni locali, Gli strumenti di raccordo alla luce dei nuovi indirizzi costituzionali*, eds. A. PIRAINO - F. TERESI, Soveria Mannelli 2004; *Regioni ed enti locali dopo la riforma del Titolo V della Costituzione*, eds. L. CHIEFFI - G. CLEMENTE DI SAN LUCA, Torino 2004; F. PIZZETTI, *L'ordinamento costituzionale italiano tra riforme da attuare e riforme da completare*, Torino 2003; C. BOTTARI, *La riforma del Titolo V, parte II della Costituzione*, Rimini 2003; *I servizi sanitari regionali tra autonomia e coerenze di sistema*, ed. R. BALDUZZI, Milano 2005.

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needs, expense autonomy, and responsibilities of each regional authority. Indeed, during that time the constitutional conflicts highlighted serious lacks, deficiencies, and other essential difficulties in the service organization related to its politicized management, which caused the failure of the public model and showed the necessity to introduce the opportune corrections in the system reform.

Anxieties and contradictions in the reform process had repercussions on the health regulation, struggling between the aspiration to assure the universality to the right to health and the exigency to valorize the regional autonomy to the extent to acknowledge to Regions a specific exclusive competence in the sector of sanitary service management, ontologically distinct from the residual legislative power.

In fact, just after the adoption of Law n. 833/1978 establishing the SSN, the legislator's behaviour appeared schizophrenic. Indeed, at first, according to Article 116 Cost., it valorized the local entities' role, especially of the city authorities, entitled to a specific role and several competences in the health service management. Later, city authorities were deprived of these competences by Legislative Decree 502/1992, even if they partially re-obtained them with Legislative Decree n. 229/1999.

On the contrary, concerning the Regions, the claim to an increasing structural and managerial autonomy has always raised several perplexities due to the overlapping of their new powers with the Central Government's exclusive legislative competence in establishing the essential levels of service providing (LEA) ex-article 117, §2, letter m), Cost.

Nevertheless, configuring a new asset, where the national health dimension is no longer necessarily the national, but also the regional one, conflicts with the national health sector vocation, showing the concrete risk that the request expressed by the Regions for further autonomy conditions in the shared legislative competences could lead to the dismantlement of the SSN and its cardinal principles.

In reality, after the 1978 reform, aimed to realize a universal and global national sanitary service, able to assure uniform and free performance to all the people, or at least covered by low prices (ticket), the SSN was accused of offering low-quality services and being excessively bureaucratized, to generate losses and corruption due to unwary management and to be submitted to political interests, to the extent that scholarship solicited a radical change to the service model. So, Legislative Decrees 502/1992[2] and 517/1993 started the process aiming to apply a managerial organization

[2] These Decrees have been anticipated by several reform efforts. See A. ROMANO TASSONE, *L'azienda sanitaria tra tecnocrazia e democrazia*, in *Sanità pubblica* 7 (1997) 387 ff.; *Unità sanitarie e istituzioni*, ed. F. MERUSI , Bologna 1982; N. AICARDI, *La sanità*, in *Trattato di diritto amministrativo*, *Diritto amministrativo speciale* I, ed. S. CASSESE Milano 2003, 641 ff.; R. FERRARA, *Organizzazione e principio di aziendalizzazione del servizio sanitario nazionale: spunti problematici*, *La dirigenza sanitaria. Amministrativisti e lavoristi a confronto*, eds. C. BOTTARI, P- TULLINI Rimini 2004, 53 ff. The 1992/1993 Reform has been elaborated in a moment of economic and political – institutional crisis, that affirmed the idea to realize a radical intervention to subtract health management from the political powers. Finally, the above-mentioned decrees introduced relevant novelties, such as, for example: a) managerialization

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for the SSN, to allow participation in accredited private operators and the affirmation of the market culture, also considering EU competition regulation. This model was partially revisited by Legislative Decree n. 229/1999[3] (and, recently, by Law Decree n. 158/2012 converted into Law n. 189/2012[4]) which, to correct and integrate the precedent Decree, recuperated the traditional framework in the relationship between institutional actors and private operators, as well as acceleratng the process aimed to apply managerial organization and privatize the structures and activities[5].

The experimentation of (ostensible) new but ineffective solutions continued until today in the attempt to assure a higher level of health protection, challenged by the sanitary austerity and by spending review aimed at waste reduction and sanitary expense rationalization.

If, on the one hand, Regions progressively acquired broad spaces for autonomy, on the other, they had to address the economic crisis that became a health crisis due to the rather strict budgetary burdens that imposed service-providing revision, structure, staff, and fund cutting, as well as increasing ticket costs.

The longterm reform process has been characterized by the proliferation of regulatory interventions aiming to solve the numerous public health problems and to the fight the Covid-19 emergency, strongly conditioned by the coordination difficulty between the governing levels and the application of due cooperation to assure the best service to the community.

The emergency multilevel management generated unhealthy competition and political divisions between powers, affecting the effectiveness of political choice and undermining measures aiming to limit the spread of contagion.

It could be expected that, from an inadequate and ineffective managerial response, due to the unpreparedness and lack of coordination between public bodies, a rethinking of competence-sharing and a thorough reflection on the Constitutional reform could arise.

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through transformation of the Local Sanitary Unities (USL) and the most relevant hospitals in Local Sanitary Undertakings (ASL) or Hospital Undertakings (AO), with public legal status and great autonomy; b) separation of buyers and providers on the basis of the market model, with the distinction between ASL and AO, their functions (respectively buying/specialistic service providing), their funding sources (the ASLs are funded on the basis of the number of persons living in their territory, while the AO are funded on the basis of the service actually provided); c) regionalization, through the attribution to the Regions of organization power, territorial service funding, and ASL control through the appointment of the Director.

[3] The correctional intervention (the so-called 'Bindi reform') responded to conservative positions, requiring the respect of fundamental SSN principles and public intervention in the health sector; it abandoned market exigencies and favoured public planning and public-private partnership.

[4] "Disposizioni urgenti per promuovere lo sviluppo del paese mediante un più alto livello di tutela della salute".

[5] Nevertheless, the reform anxiety did not give satisfying results, leaving several problems unsolved. On the correctional intervention results, I. CAVICCHI, *Sanità. Un libro bianco per discutere*, Bari 2005; N. AICARDI (nt. 2); *Il nuovo servizio sanitario nazionale*, ed. F. ROVERSI MONACO, Rimini 2000; G. SANVITI, *Artt. 3 e 3* bis, *d.lgs n. 502/1992 (Commento)*, *Ibidem*, 108 ff.; G. CILIONE, *Diritto sanitario*, Rimini 2019.

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I.2 Problems concerning competence sharing in the public health sector.

From 1990 onward, in Italy and the other European countries, the competence transfer from the Central Government to the Regions led to the acknowledgement of organization and management autonomy of health services, as well as the availability (and the use responsibility) of competence, financial and political instruments. Starting from that period, SSN fragmentation in several regional systems generated significant differences between the organization frameworks and services, from the quantitative and qualitative perspective, increasingly evident throughout the country.

Undoubtedly, art. 117, §3 Const., on the same lines as the previous text, confirming the competence shared framework in the sectors of health protection, hygiene, the public health system (before health assistance), remarked the strategic position assigned to the Regions, at the end of the process started by Legislative Decree n. 502/1992, consolidated by Legislative Decree n. 229/1999 and completed by the above-mentioned Law n. 189/2012.

The provision must be read jointly with articles 117, §2, 120, § 2 e 118, §1 Const., taking into account the Constitutional Court interpretation, which, from 2003[6], elevated 'sectors' to the rank of 'values', intercepting national and regional competences, suggesting the adoption of a more flexible system, able to interpret the new multilevel governance exigencies in the perspective of political and institutional supranational and European pressures[7], aiming to protect the right to health and citizen expectations, to which the State and the health policy and organization are of service[8].

Early, the organizational issue progressively lost importance in the political and institutional debate, concentrated on the problem of shared competences ex-art. 117,

[6] Corte cost. 1 October 2003, n. 303.

[7] Cf., Corte cost. 26 giugno 2002, n. 282. F. PIZZETTI, *Le nuove esigenze di Governance in un sistema policentrico esploso*, in *Le Regioni* XXIX (2001), 1153 ff.; M. LUCIANI, *I diritti costituzionali tra Stato e regioni (a proposito dell'art. 117, comma 2, lett. m), della Costituzione*, in *Sanità pubblica* 12 (2002) 1025 ff. On the reasons for exclusive competence attribution to the Central Government, which could be exercised also in the transversal sectors, see C.E. GALLO, *La potestà legislativa regionale concorrente, i diritti fondamentali ed i limiti alla discrezionalità del legislatore davanti alla Corte costituzionale (nota a Corte cost. 26 giugno 2002, n. 282)*, in *Foro amm. CDS* 1 (2002) 2791 ff.; V. MOLASCHI, *Livelli essenziali delle prestazioni e LEA sanitari: prime indicazioni della giurisprudenza di merito (commento a TAR Lazio, sez. III, 10 luglio 2002, n. 6252)*, in *Foro amm. TAR* 2 (2003) 181 ff.; G. CREPALDI, *Dai LEA ai livelli essenziali delle prestazioni concernenti i diritti civili e sociali*, in *La tutela della salute tra tecnica e potere amministrativo*, Milano 2006, 49 ff. This interpretation, related to essential service levels, refers to health assistance and could be extended to other sectors, such as the environment and ecosystem protection, with the following attribution to the Regions of organizational and managerial competences.

[8] In line with the constitutional provisions protecting unity in differentiation «la formula "servizio sanitario nazionale" deve essere (necessariamente) decodificata (nel senso che) sono ormai le singole regioni a dover delineare, nel concreto, il contenuto plurale del servizio, e pertanto della rete di prestazioni che, con carattere di effettività ed in regime di sostanziale eguaglianza, debbono essere erogate ai cittadini». See, R. FERRARA (nt. 2) 135.

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§3 Const., generating multilevel conflicts between the Central Government and between the Regions.

Attribution conflicts between institutional actors, that is Regions and Central Government, charged to assure care, providing uniformity on the whole national territory, and to verify respect of the health expense burden, consist essentially in the establishment of assistance essential levels (LEA)[9] provided by the Regions and yearly monitored by the Ministry of Health regarding the adequacy, timing and compliance with further criteria determining the amount of resources to devolve to the SSN (attracting several public and private interests, coming also from actors stipulating conventions with the SSN). Due to the regional responsibility in managing the service-providing, conflicts between virtuous and less performing Regions also concern budget sharing[10].

With specific reference to the article 117, §2, letter (m, Const., the Constitutional Court recently clarified that the competence sharing in the health protection sector could be relatively 'mobile', and it concretely depends on the legislative choices aiming to favour coordination and cooperation between the Central Governments and Regions formalized within the agreements reached within the Conference, including Central Government and Regions. As a consequence, apart from the formal attribution of the LEA to the Central Government, it is well evident that the establishment of regional LEA needs necessarily involves Regions, with whom the Central Government should have a relationship based on sincere cooperation and due collaboration to assure the effectiveness of the right to health and healthcare[11].

Nevertheless, with this judgment, the Constitutional Court had no intention of slyly altering the organization of competences, which remains a stable point of reference in the Court's decisions, as reaffirmed by the Court in Judgment n. 37/2021 on the constitutional legitimacy of a regional law adopted by the Valle d'Aosta[12]. Through this judgment, the Constitutional Court would stem the potential negative effects of the exaggerated autonomy progressively assumed by some Regions, re-establishing

[9] They consist in a list of essential health services divided into prevention and public health; territorial assistance and hospital assistance *ex* Decree of the President of the Council of Ministries 2017 defined and updated by the Ministry of Health.

[10] Cf. Corte dei conti, sez. contr. riun., *Rapporto sul coordinamento della finanza pubblica*, 2020. G. URBANO, *Equilibrio di bilancio e governance sanitaria*, Bari 2016.

[11] Corte Cost. 21/03/2017, n. 169.

[12] Actually, through this judgment, the Constitutional Court declared the constitutional illegitimacy of Articles 1, 2, 4, § 1-3 of the Law of Valle D'Aosta Region 11/2020, as it was devoted to impeding the immediate and direct application on the regional territory of the national measures of Covid-19 contagion containment. To this aim, the Constitutional Court clarified that the exclusive national competence on the international prophylaxis, ex-article 117, §2, letter q), Const., is in conflict with the 'adattamento della normativa statale alla realtà regionale, che non sia stato preventivamente stabilito dalla legislazione statale; unica competente sia a normare la materia in via legislativa e regolamentare, sia ad allocare la relativa funzione amministrativa, anche in forza, quanto alle autonomie speciali, del perdurante principio del parallelismo' .

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the equilibrium between roles and powers attributed to the different levels of government in the field of health protection and public health management that have to be protected.
However, significant protests concerned the allocation criteria and the shortfall accumulated by some Regions to the detriment of those with more effective health systems, reclaiming an acceleration of the fiscal federalism process.
Countermeasures adopted by the Government in the 2006 'Health Pact' consisted in the obligation for Regions presenting budget difficulties to sign up to a repayment plan and, in case of its non-accomplishment, the SSR being put under external administration. In most cases, these countermeasures were unable to lead the Regions outside the crisis to establish the financial equilibrium, with negative reflections on the service-provider's organization and quality, generating migration towards Regions with more effective and reliable health systems.
In this situation, the maintenance of the health regional framework inspired by solidarity is at risk because some Regions claim greater autonomy in the perspective of differentiated regionalism.
Nevertheless, this model generates several perplexities due to the implications in terms of national and regional administration and fundamental rights protections and, especially, in terms of the right to health, making multilevel cooperation more difficult and highlighting limits and difficulties in the realization of reforms able to obstacle the pursued objective[13].

I.3 The supranational dimension of the right to health: reflections on the promotion of inter-institutional governance and European solidarity.

While in Italy the debate about the reform of Title V, II Part, Const. goes on, mainly after the pandemic outbreak and developments, significant oscillations persist between the exigencies to centralize and decentralize competences, i.e., between national unity and regional differentiation. More specifically, some Regions have recently exploited the opportunity offered by article 117, §8 Const., to stipulate agreements between Regions with the purpose of optimizing the results from shared bodies exercising joint functions for health protection. This solution is not convincing, as there is the actual risk that stipulating agreements could become a concrete possibility only for some Regions that did not stop demanding more autonomy also during the pandemic.
These perplexities increase if the problem is analyzed in its supranational dimension, where the right to health and its protection acquired great relevance after the covid-

[13] See R. CARIDÀ, *Il processo di differenziazione regionale ex art. 116, terzo comma, della Costituzione: la natura delle funzioni e i vincoli costituzionali*, in *Nuove Autonomie*, XXIX (2020) 159 ff. A. LUCARELLI, *Regionalismo differenziato e incostituzionalità diffuse*, in *Dir. pubbl. eur.* Rassegna on-line, 2/2019; L. VANDELLI, *Il regionalismo differenziato tra peculiarità territoriali e coesione nazionale*, in *Astrid Rassegna* n. 11/2018.

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19 emergency, which highlighted several weaknesses in the Italian SSN, with repercussions on social and health guarantees.

Contemporary changing, and global, society is facing well-known and new problems suggesting the adoption of a different approach to health protection and governance and the identification of tools able to favour common objective accomplishment, also increasing the investments in the sustainability of health systems, such as fundamental values and key elements of economic growth[14].

As is well-known, the discipline of the service organization and quality are traditionally reserved to the single Member States' legislation, strongly defending their competences and decisional autonomy in the planning and management of a health emergency (*ex* art. 168, §7, TFEU). The EU has a shared competence in the "common safety concerns in public health matters, for the aspects defined in this Treaty", and competence to carry out actions to support, coordinate or supplement the actions on the "protection and improvement of human health"[15].

The drastic Member States' position against an EU competence enlargement in the health sector has been strengthened by the competence framework coming from the Lisbon Treaty that has been firmly criticized[16], even if the events following the pandemic outbreak and spread showed the necessity for greater EU involvement based on an integrated approach aimed to realize more efficient cooperation able to assure a coordinated and coherent answer over the whole EU territory. This solution, justified by the need to assure a high level of protection of human health, confirms the suitability of acknowledging the broader EU initiative and intervention spaces, emancipating it from the secondary and residual role to complete, solicit, and sustain the Member States' action, attributing it new responsibilities[17].

This awareness sinks its roots in the 2007 economic and social crisis coming from the

[14] See Corte dei Conti, *La mobilità sanitaria: l'assistenza transfrontaliera*, in *www.corteconti.it*.

[15] See art. 168, §3 TFEU, articles 196 (Civil Protection) and 222 (Solidarity Clause). See Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC.

[16] According to M. L. TUFANO, *Il ruolo della Commissione nella governance europea: quali prospettive?*, in *DUE* XVII (2012) 133, 145 f., it appears «animat(o) più da un'esigenza di certezza del diritto che da un'ottica di efficacia (...) la quale ha finito col generare una serie di incongruenze». See also ID., *Atti di organi e organismi dell'Unione europea, discrezionalità tecnica e sindacato giurisdizionale*, in Aa. Vv., *Liber Amicorum Antonio Tizzano. De la Cour CECA à la Cour de l'Union: le long parcours de la justice européenne*, Giappichelli, Torino 2018, 993, 1005 ff.

[17] On the basis of a new paradigm founded on the multiform and polysemy of "Europeanization". See M. ROMANIELLO, *Beyond the Constitutiona 'Bicameral Blueprint': Europeanization and national identities in Belgium*, in *Democracy and Subsdiarity in the EU. National Parliaments, Regions and Civil Society in the Decision-Making Process* eds. M. CARTABIA, N. LUPO, A. SIMONCINI, Bologna 2013, 285 ff.; *Europeanization: New Research Agendas, Basingstoke* eds. P. GRAZIANO, M. VINK, London 2007; C. M. RADAELLI, *Whither Europeanization? Concept stretching and substantive change*, in *European Integration online Papers (EIoP)* (2000) 8. On the Commission role and activity during the sanitary emergency to protect the common interest respecting the limits imposed by the Article 168 TFEU, see. A. RENDA, R. J. CASTRO, *Towards stronger EU governance of health threats after the COVID-19 pandemic*, in *European Journal of Risk* 11 (2020) 1 ff.; A. M. PACCES, M. WEIMER, *From diversity to coordination: A European approach to Covid 19*, in *Amsterdam Law School Research Paper* No. 2020-10, 15 April 2020.

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degeneration of economic globalization[18], a phenomenon overcoming the national borders to extend into a world space, whose collateral effects spread without stopping until now, as well as in transborder mobility, that, starting from 2013 mainly in Italy, generated problems in the relationship between the citizens and their "national contact points"[19] and relationship difficulties within the different networks concerning the identification of excellent structures in the different medicine sectors in the EU[20].

Furthermore, the provision of Art. 168, §5 TFEU establishes that "the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, may also adopt incentive measures designed to protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health".

It highlights the strict link between solidarity and the right to health that urges to review the roles and relationship based on the principle of loyal cooperation, regardless of formal competence sharing, overcoming the limits of autonomist management.

The postponement of the launch of the Conference on the European future, launched on 9 May 2021, on the one hand, pushes away the hypothesis of a Treaty revision ex 48 TEU[21], and on the other hand, leads to review the competence framework to bridge the EU structural lacks and to confer different and more incisive action and reaction powers, overcoming strict Treaty limits[22].

Persistent tensions at the national and European levels could be overcome by attributing to the principles the authority that, especially in emergencies, assure effectiveness in their application. The issue is not correctly addressed, and it is the result of methodological mistakes that, concerning health protection, leverage on the

[18] See S. BATTINI, *La globalizzazione del diritto pubblico*, in *Riv. trim. dir. pubbl.*, 56 (2006) 325 ff. M. D'ALBERTI, *La crisi globale e la sorte dei diritti fondamentali*, in *Riv. it. sc. giur.* (2013) 195 ff.

[19] See Corte dei Conti (nt. 12) "A partire dagli anni Novanta, le disposizioni normative, che hanno modificato il SSN nella governance ma, soprattutto, il sistema di finanziamento assieme ai provvedimenti in materia di federalismo fiscale e alle misure intraprese per la razionalizzazione della spesa pubblica e per la riduzione dei disavanzi regionali in sanità, hanno prodotto un forte ridimensionamento dell'investimento statale". Investment reduction created problems for healthcare budget management and "un significativo sbilanciamento finanziario dell'Italia con posizioni di debito che eccedono quelle di credito".

[20] *Ibidem*. The Court of Auditors underlined the need "di coordinamento normativo e di armonizzazione della disciplina europea sull'assistenza transfrontaliera contenuta nella direttiva 2011/24/UE e nel Regolamento 2004/833".

[21] See. V. DELHOMME, *Emancipating Health from the Internal Market: For a Stronger EU (Legislative) Competence in Public Health*, in *European Journal of Risk Regulation* 11 (2020) 1 ff.

[22] See General Secretariat of the Council, Doc. 6038/20, Council Conclusions on COVID-19, 13 February 2020, point 15, lett. b); Conclusions by the President of the European Council following the video conference with members of the European Council on COVID-19, 17 March 2020.

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requirement of State unity and inseparability that is usually considered as prevalent on the territorial autonomy but which, on the contrary, should be considered a value to be defended and a fundamental wealth.

Unity and autonomy are not incompatible and contrasting values, but, on the contrary, one presupposes the other, as they are jointly and teleologically oriented to the citizen's health, a value that they pursue together. As a consequence, sovereignty does not belong exclusively to the State and has to be exercised in compliance with fundamental principles and values during the emergency. It implies the necessity to redefine the State and role of political power in the process of health governance concerning both the organization and planning of the health system and the application of the emergency management plan.

In a "fluid" society, dominated by the uncertainty of the risk seriousness threatening the public health, the EU could become a driver of change in a phase of heavy depression where institutional equilibrium is at stake.

In this scenario, where the process of power reallocation and restructuring is realized through the valorization of the inclusion/participation principle by cooperation and coordination[23], focusing on autonomy in a sector characterized by multiple, inter-disciplinary and inter-dependent competences, appear useful and must be shared by several institutional levels.

To overcome the health crisis, flexible, effective, and adequate solutions are necessary, together with adaptability to the territorial needs and exigencies, which implies the adoption of a model of institutional governance conceived as "rules, processes and behaviour that affect the way in which powers are exercised at European level, particularly as regards openness, participation, accountability, effectiveness and coherence[24]".

Solidarity assumed a fundamental weight in the debate at the European level on the relationship between the Member States, suggesting the adoption of an alternative model inspired by the principle of sincere cooperation and founded on the integration of competence at all institutional levels.

In this perspective, it is hoping that EU, Member States and Regions will create a symbiotic community, aimed not only to contrast the impelling and endemic health emergency but also to protect the fundamental values shared by most of the Member States[25].

To overcome the opposition expressed by several Member States, enhanced cooperation could be a useful instrument if used as a measure of differentiated

[23] L. HOOGHE, G. MARKS, *Types of multi-level governance*, in *European integration online papers (EIOP)* (2001) 11; V. DELHOMME (nt. 19) 8 ff.

[24] See COM (2001) 428 final/2, 25.07.2001 p. 8, footnote 1.

[25] See COM (2020) 724 final, 11.11.2020, *Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats*.

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integration of last resort[26], exploiting the potentiality of this instrument that "offers solutions to common problems with the convenience of using the Union institutional and administrative support" but "…has not eliminated the pursuit of Member States for solutions outside the EU Treaties"[27].

To this end, the European Parliament recommended that "the Commission play an active role in all stages of enhanced cooperation from the proposal through the deliberations to the implementation of enhanced cooperation", affirms that "the unity of EU institutions should be maintained and that enhanced cooperation should not lead to the creation of parallel institutional arrangements, but could allow specific bodies to be established where appropriate within the EU legal framework and without prejudice to the competences and role of the Union institutions and bodies"[28], and especially stresses "the need for the Member States participating in enhanced cooperation to include those regions that have legislative powers in matters that affect them, with a view to respecting the internal division of powers and reinforcing the social legitimacy of such enhanced cooperation"[29].

The exaltation of the value and contribution of existent and new cooperation instruments could constitute an effective remedy to conciliate unity and differentiation and to eliminate territorial disparities, acting as a stimulus to invest in universalistic public health, since they aim to identify organizational models and promote virtuous processes for the spread of the wellness culture[30].

Cooperation and sharing[31] are the basis of the global perspective leading to a role systematization and to competence sharing, able to assure uniform application of fundamental rights and liberties, favouring the elaboration of innovative and more effective models of social development which should be differentiated on the basis of the consistency and effectiveness of multilevel protection[32].

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[26] European Parliament, *Report on the implementation of the Treaty provisions concerning enhanced cooperation*, (2018/2112(INI)), 28.1.2019, https://www.europarl.europa.eu/doceo/document/A-8-2019-0038_EN.html.

[27] *Ibidem*, point 19.

[28] *Ibidem*, point 20.

[29] *Ibidem*, point 22.

[30] S. CASSESE, *L'arena pubblica. Nuovi paradigmi per lo Stato*, in *Riv. trim. dir. pubbl.* 51 (2001) p. 601 ff. L. TORCHIA, *Sistemi di welfare e federalismo*, in *Quad. Cost.* XXII (2002) 274.

[31] L. VANDELLI, *Riflessioni a dieci anni dalla riforma del Titolo V: quali prospettive per il regionalismo italiano?*, in *Le Regioni* XXXIX (2011).

[32] S. CASSESE, *Concentrazione e dispersione dei poteri pubblici*, in *Studi in onore di Biscaretti di Ruffia* I, Milano 1987, 155; R. CAVALLO PERIN, *L'organizzazione delle pubbliche amministrazioni e l'integrazione europea*, in *L'organizzazione delle pubbliche amministrazioni tra stato nazionale e integrazione europea*, eds. R. CAVALLO PERIN, A. POLICE, F. SAITTA, Firenze 2016, 3 ff. referring to G. TOSATTI, *Sicurezza pubblica, organizzazione centrale e periferica*, (all. B), in *Amministrare* XLV (2015) 91 ff.; R. CAVALLO PERIN, G. RACCA, *Cooperazione amministrativa europea*, in *Dig. disc. pubbl.*, Agg., Torino 2017, p. 191 ff. underline that cooperation on issues of common interest aims to concretize the law and the good administration, that, overcoming strict Treaty limits, realises a "coesione tra il diritto e la realtà sociale" (thus, M. MACCHIA, *La cooperazione amministrativa come "questione di interesse comune,"* in *Lo spazio amministrativo europeo. Le pubbliche amministrazioni dopo il Trattato di Lisbona*, eds. M. P. CHITI, A. NATALINI, Bologna, 2012, 94; B. NASCIMBENE, *Unione europea tra unità e pluralità degli ordinamenti giuridici*, in *Attualità e*

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The proposal to establish an EU Health Emergency Preparedness and Response Authority (HERA) [33] should be interpreted in this perspective, as well as the scientific and factual data on the sanitary emergency, suggesting the necessity to invest globally to strengthen the ability to forecast on the part of Governments and international Institutions in the health sector. As a consequence, it could be useful to set up an EU *task force*[34] that could steer the Member States' sanitary policies through effective methods and instruments.

Part II
Administrative multilevel networks after the Covid-19 emergency: from joint procurement procedures to Advanced Purchase Agreements.

II.1 *Aggregated Procurement Procedures within the Public Procurement Directives.*
As has been analyzed in Part I, the principal obstacle to the EU acquisition of an effective coordination role in the health sector is the lack and confusion of competences. One of the methods the EU resorted to in the effort to strengthen its role in the health sector is inducing the States to share or centralize the procurement procedures crucial to assure service-providing but which are also very onerous in terms of the costs, time, and human resource to be involved. Join procurements were implicitly admitted by Directive 2004/18/EU[35] and were experienced in the exploitation of some EU-funded projects[36].
Directive 2014/24/EU[37] explicitly regulates them to promote the aggregation of procurement procedures of goods, services, and works as well as to foster the

necessità del pensiero di Santi Romano, eds. R. CAVALLO PERIN, G. COLOMBINI, F. MERUSI, A. POLICE, A. ROMANO, Napoli 2019, 37.

[33] COM (2020) 724 final, 11.11.2020.

[34] P. DE PAOLI, *Guardare oltre il covid-19: proposte per il rinnovamento del sistema sanitario nazionale*, in *www.giustiziainsieme.it*. Today, the European Centre on European Centre for Disease Prevention and Control (ECDC) has the function of collecting and analysing data and scientific advice but not to coordinate functions.

[35] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts, recital n. 9 "In view of the diversity of public works contracts, contracting authorities should be able to make provision for contracts for the design and execution of work to be awarded either separately or jointly. It is not the intention of this Directive to prescribe either joint or separate contract awards. The decision to award contracts separately or jointly must be determined by qualitative and economic criteria, which may be defined by national law". See also article 15.

[36] See, for example, the Healthy Ageing - Public Procurement of Innovations (HAPPI) project funded by the EU Commission (DG Enterprise) within the Call "*Supporting Public Procurement of Innovative Solutions: Networking and Financing Procurement*". The project aimed to establish a strategic cooperation among healthcare purchasing authorities of several Member States.

[37] Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC.

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innovation of procurement procedures, also using ICT tools[38]. More specifically, Recital 71 ff., after having clarified that the provisions concerning central purchasing bodies[39] should in no way prevent the current practices of occasional joint procurement[40], underlines that certain features of joint procurement should be clarified because of the important role they may play, not least in connection with innovative projects[41]. Recital 73 makes specific reference to the joint awarding of public contracts by contracting authorities from different Member States[42]. It underlines that new rules on cross-border joint procurement should be established to facilitate cooperation between contracting authorities and enhancing the benefits of

[38] S. PONZIO, *Joint Procurement and Innovation in The New Eu Directive and in Some Eu-Funded Projects*, in *Ius Publicum Network Review* 2 (2015) 1 ff.

[39] According to Article 2, §1, n. 14 "'centralised purchasing activities' means activities conducted on a permanent basis, in one of the following forms: (a) the acquisition of supplies and/or services intended for contracting authorities, (b) the award of public contracts or the conclusion of framework agreements for works, supplies or services intended for contracting authorities». According to Article 37, Member States may provide that contracting authorities may acquire supplies and/or services from a central purchasing body offering the centralised purchasing activity. Member States may also provide that contracting authorities may acquire works, supplies and services by using contracts awarded by a central purchasing body (CPB), by using dynamic purchasing systems operated by a central purchasing body or by using a framework agreement concluded by a central purchasing body offering the centralised purchasing activity. Contracting authorities may, without applying the procedures provided for in the Directive, award a public service contract for the provision of centralised purchasing activities to a central purchasing body". In Italy, the CPB is Consip S.p.A., a society owned by the Ministry of Economy.

[40] It refers, for example, to less institutionalised and systematic common purchasing or the established practice of having recourse to service providers that prepare and manage procurement procedures on behalf of and for the a contracting authority under its instructions.

[41] Recital 71 specifies that joint procurement can take many different forms, ranging from coordinated procurement through the preparation of common technical specifications for works, supplies or services that will be procured by a number of contracting authorities, each conducting a separate procurement procedure, to situations where the contracting authorities concerned jointly conduct one procurement procedure either by acting together or by entrusting one contracting authority with the management of the procurement procedure on behalf of all contracting authorities. Where several contracting authorities are jointly conducting a procurement procedure, they should be jointly responsible for fulfilling their obligations under this Directive. However, where only parts of the procurement procedure are jointly conducted by the contracting authorities, joint responsibility should apply only to those parts of the procedure that have been carried out together. Each contracting authority should be solely responsible in respect of procedures or parts of procedures it conducts on its own, such as the awarding of a contract, the conclusion of a framework agreement, the operation of a dynamic purchasing system, the reopening of competition under a framework agreement or the determination of which of the economic operators being party to a framework agreement shall perform a given task. C. BOVIS, *The New Public Procurement Regime: A Different Perspective on the Integration of Public Markets of the European Union*, in *European Public Law* 12 (2006) 73 ff., 78; IDEM, *Public Service Partnerships as Instruments of Public Sector Management in the European Union*, in *Colum. J. Eur. L* 18 (2012) 473 ff., 474 f., 478 ff. On jointly controlled in-house entities, see Judgement of the Court of Justice of 13 November 2008, C-324/07, *Coditel Brabant SA v. Commune d'Uccle, Région de Bruxelles- Capitale;* 9 June 2009, C- 480/06, *Commission c. Germany.* For an analysis of this case-law, C. BOVIS, *Future Directions in Public Service Partnership in the EU*, in *EBLR* 24 (2013) 1 ff., 31 ff.; R. CARANTA, *The Changes to the Public Contract Directives and the Story They Tell About How EU Law Works*, in *CML Rev*. 52 (2015) 391 ff., 439 ff.

[42] According to Recital 73 "… Directive 2004/18/EC implicitly allowed for cross-border joint public procurement…".

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the internal market by creating cross-border business opportunities for the supplier and service provider market in terms of economies of scale and risk-benefit sharing.
However, contracting authorities should not make use of the possibilities of cross-border joint procurement to circumvent mandatory public law rules, in conformity with Union law, which applies to them in the Member State where they are located. Such rules might include, for example, provisions on transparency and access to documents or specific requirements for the traceability of sensitive supplies. On these premises, while Article 38 disciplines 'Occasional joint procurement'[43], Article 39 concerns 'Procurement involving contracting authorities from the different Member States'. The Article impedes a Member State from prohibiting its contracting authorities from using centralized purchasing activities offered by central purchasing bodies (CPBs) located in another Member State. The provision of centralized purchasing activities by a CPB located in another Member State is conducted following the national provisions of the Member State where the central purchasing body is located[44]. According to paragraph 4,
"several contracting authorities from different Member States may jointly award a public contract, conclude a framework agreement or operate a dynamic purchasing system[45]".

[43]According to Article 38 "Two or more contracting authorities may agree to perform certain specific procurements jointly. Where the conduct of a procurement procedure in its entirety is carried out jointly in the name and on behalf of all the contracting authorities concerned, they shall be jointly responsible for fulfilling their obligations pursuant to this Directive. This applies also in cases where one contracting authority manages the procedure, acting on its own behalf and on the behalf of the other contracting authorities concerned. Where the conduct of a procurement procedure is not in its entirety carried out in the name and on behalf of the contracting authorities concerned, they shall be jointly responsible only for those parts carried out jointly. Each contracting authority shall have sole responsibility for fulfilling its obligations pursuant to this Directive in respect of the parts it conducts in its own name and on its own behalf".

[44] The national provisions of the Member State where the central purchasing body is located also apply to the following: (a) the award of a contract under a dynamic purchasing system; (b) the conduct of a reopening of competition under a framework agreement; (c) the determination pursuant to points (a) or (b) of Article 33(4) of which of the economic operators, party to the framework agreement, perform a given task.

[45] According to Article 33, a framework agreement means an agreement between one or more contracting authorities and one or more economic operators, the purpose of which is to establish the terms governing contracts to be awarded during a given period, in particular with regard to price and, where appropriate, the quantity envisaged. The term of a framework agreement shall not exceed four years, save in exceptional cases duly justified, in particular by the subject of the framework agreement. According to Article 34, the dynamic purchasing system will operate as a completely electronic process and will be open throughout the period of validity of the purchasing system to any economic operator that satisfies the selection criteria. It may be divided into categories of products, works or services that are objectively defined on the basis of characteristics of the procurement to be undertaken under the category concerned. Such characteristics may include reference to the maximum allowable size of the subsequent specific contracts or to a specific geographic area in which subsequent specific contracts will be performed. Contracting authorities follow the rules of the restricted procedure. Unless the necessary elements have been regulated by an international agreement concluded between the Member States concerned, the participating contracting authorities conclude an agreement that determines: (a) the responsibilities of the parties and the relevant applicable national provisions; (b) the internal organisation of the

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Through this mechanism, a significant change in the procurement organizational models is pursued, based on the aggregation of the award procedures and managed by CPBs. Aggregation allows sharing of professional skills (legal, economic, technical, engineering) and favours the smarter use of innovative contractual instruments, such as framework agreements and dynamic purchase systems[46]. Furthermore, contracting authorities from different Member States could establish joint entities entitled to carry out the award procedure[47].

Cross-border joint procurements could represent a useful tool to reduce the competition between CPBs of different Member States, with divergent legal frameworks, in the procurement of essential goods and services. It could strengthen the professional competences of civil servants managing the procurement procedures and combat phenomena such as corruption and conflict of interests[48].

As health is a sector of limited cross-border dimensions "provided within a particular context that varies widely amongst Member States, due to different cultural traditions"[49], the regulation established by Directive 2014/24 provides for several exceptions to this sector[50]. As a consequence, excepting the EU-funded projects, joint procurement procedures between States' contracting authorities have been scarcely used in the health sector.

Even if in the "Guidance on using the public procurement framework in the emergency related to the COVID-19 crisis"[51], the Commission encouraged public buyers to procure jointly, applying the Directive 2014/24 rules, Member States preferred to act unilaterally, in a sort of "healthcare sovereignism".

II.2 Procurement procedures directly managed by the European Commission on the behalf of Member States.

In some specific cases, the European Commission directly manages joint procurement on behalf of Member States. These procedures were specifically employed in the health sector after the 2009 A/H1N1 pandemic (swine flu) when the Council of European Union invited the European Commission to set up

procurement procedure, including the management of the procedure, the distribution of the works, supplies or services to be procured, and the conclusion of contracts.

[46] S. PONZIO (nt. 38) 11.

[47] The Directive explicitly refers to the European grouping of territorial cooperation (EGTC). As is well-known, EGTC was created in the context of cohesion and territorial cooperation as an instrument to promote and facilitate cooperation, mainly about territorial authorities. See Regulation (EU) No 1302/2013 of the European Parliament and of the Council of 17 December 2013 amending Regulation (EC) No 1082/2006 on a European grouping of territorial cooperation (EGTC) as regards the clarification, simplification and improvement of the establishment and functioning of such groupings.

[48] S. PONZIO (nt. 38) 28 ff.

[49] Cf. Recital 114 Directive 2014/24.

[50] Article 74 ff. and Annex XIV related to "Social and other specific services". R. CARANTA (nt. 39) 426 ff.

[51] COM (2020/C 108 I/01), 1.4.2020, p. 3.

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"a mechanism for joint procurement of vaccines and antiviral medication which allows the Member States, on a voluntary basis, common acquisition of these products or common approaches to contract negotiations with the industry, clearly addressing issues such as liability, availability and price of medicinal products as well as confidentiality"[52].

From this perspective, Regulation No 966/2012 on the Financial Rules Applicable to the General Budget of the Union, Article 104, established that "where a public contract or framework contract is necessary for the implementation of a joint action between an institution and one or more contracting authorities from Member States, the procurement procedure may be carried out jointly by the institution and the contracting authorities, in certain situations, which are to be specified in the delegated acts adopted pursuant to [the] Regulation. Joint procurement may be conducted with European Free Trade Area (EFTA) States[53], and Union candidate countries, if this possibility has been specifically provided for in a bilateral or multilateral treaty".

Decision No 1082/2013/EU on serious cross-border threats to health, article 5, establishes that "the institutions of the Union and any Member States which so desire may engage in a joint procurement procedure conducted pursuant to the third subparagraph of Article 104(1) of Regulation (EU, Euratom) No 966/2012 …, with a view to the advance purchase of medical countermeasures for serious cross-border threats to health"[54].

According to Article 5, §3 "the joint procurement procedure…shall be preceded by a Joint Procurement Agreement between the Parties determining the practical arrangements governing that procedure, and the decision-making process with regard to the choice of the procedure, the assessment of the tenders and the award of the contract".

To apply this disposal, in 2014, the Commission adopted the "Decision on approval of the Joint Procurement Agreement to procure medical countermeasures"[55] (JPA). In

[52] 3032nd Council meeting General Affairs Brussels, Conclusions, 13 September 2010, doc. 12655/2010, 28.07.2010 "Lessons to be learned from the A/H1N1 pandemic"; 3053rd Employment, Social Policy Health and Consumer Affairs Council Meeting, Council conclusions *Innovative approaches for chronic diseases in public health and healthcare systems*, 7 December 2010. See also European Parliament resolution of 8 March 2011 on reducing health inequalities in the EU (2010/2089(INI)).

[53] EFTA States are Island, Norway, Liechtenstein, and Switzerland.

[54] According to paragraph 2, "The joint procurement procedure referred to in paragraph 1 shall comply with the following conditions: (a) participation in the joint procurement procedure is open to all Member States until the launch of the procedure; (b) the rights and obligations of Member States not participating in the joint procurement are respected, in particular those relating to the protection and improvement of human health; (c) the joint procurement does not affect the internal market, does not constitute discrimination or a restriction of trade or does not cause distortion of competition; (d) the joint procurement does not have any direct financial impact on the budget of Member States not participating in the joint procurement».

[55] Commission Decision C(2014) 2258 final of 10.4.2014.

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the document "Considerations on the legal basis and the legal nature of the Joint Procurement"[56], the Commission clarifies that "from the point of view of the Union law, the joint procurement agreement is intended to implement a provision of a legislative act, namely, Article 5 of Decision 1082/2013/EU. As it is concluded between the Commission and the participating states, it is considered by the Commission as a budgetary implementing measure of Decision 1082/2013/EU. Its unusual character is explained by the fact that it is a measure adopted in common by the Commission and the participating states. In line with the provision of Article 168 paragraph 5, the Commission will implement the decisions taken by the Member States and coordinate the joint procurement procedure. The Joint Procurement Agreement is concluded pursuant to the Financial Regulation and Decision 1082/2013/EU, and falls entirely within the subject matter of the Treaties. These acts provide explicitly that they are governed by Union law (including principles common to the Member States), and any disputes are subject to exclusive jurisdiction of the Court of Justice. It is not an international treaty, in the meaning of the Vienna Convention on the Law of Treaties".

Today the JPA is specifically disciplined by Regulation 2018/1046 on the financial rules applicable to the general budget of the Union and repealing Regulation No 966/2012. Article 165, §2 of Regulation 2018/1046 specifies that "Where the share pertaining to or managed by the contracting authority of a Member State in the total estimated value of the contract is equal to or above 50 %, or in other duly justified cases, the Union institution may decide that the procedural rules applicable to the contracting authority of a Member State shall apply to the joint procurement, provided that those rules may be considered as equivalent to those of the Union institution. The Union institution and the contracting authority from a Member State, an EFTA State or a Union candidate country concerned by the joint procurement shall agree in particular upon the detailed practical arrangements for the evaluation of the requests for participation or of the tenders, the award of the contract, the law applicable to the contract and the competent court for hearing disputes".

As a consequence, the JPA could be considered as a 'partnership agreement', a 'contract' aimeing to establish the practical arrangements of joint procedures between the Commission and participating Member States. In the relationship between the Member States, the JPA remembers – in a 'quasi-federal perspective – the 'framework agreements' stipulated in Italy between States and Regions and between Regions[57].

Concerning the JPA discipline, according to Article 1, §5, JPA is without prejudice to the right of the Contracting Parties to carry out procurement procedures outside this Agreement, even where such procedures involve the procurement of medical

[56] EUROPEAN COMMISSION, *Considerations on the legal basis and the legal nature of the Joint Procurement*, 10 April 2014, p. 1 ss., https://ec.europa.eu/health/sites/health/files/preparedness_response/docs/jpa_legal_nature_en.pdf

[57] See *supra*, Part I, paragraph 3.

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countermeasures which form the subject of a joint procurement procedure or a framework contract or involve economic operators or contractors who are tendering for or have signed, a framework contract under a joint procurement procedure under this Agreement.

Regarding operative issues, Article 13 establishes that a procurement procedure can start if at least five Contracting Parties, including the Commission, participate. The rule aims to ensure smaller Member States an launch a procedure even if the major States are not interested in purchasing medicines and vaccines.

JPA management is attributed to the *Joint Procurement Agreement Steering Committee* (JPASC) [58], composed of one representative of the Commission and one representative of each Contracting Party. Management of single procedures and the elaboration of technical specifications and general allocation criteria are attributed to the *Specific Procurement Procedure Steering Committees* (SPPSC o *Steering Committees*)[59], composed of one representative of Member States participating in the procedure[60].

The Commission is charged with the conduct of the joint procurement procedures, including the award of the framework or direct contracts, and the management of the framework contracts, including the signature of any amendment of a non-substantial nature[61], as well as with the adoption of the award decision, after approval by the Specific Procurement Procedure Steering Committee[62]. After the award decision is adopted, the participating Contracting Parties sign the contract[63], previously approved by the SPPSC. Framework contracts establish the general supply conditions, while specific contracts, concluded between individual participating Contracting Parties and the JPA contractors that are parties to these framework contracts[64], establish the details[65]. According to Article 17,

"the frequency with which available amounts of medical countermeasures are allocated between participating Contracting Parties ('the generally applicable allocation criteria') shall be submitted to the SPPSC for approval[66]. The Contracting Parties shall receive the total quantity of the medical countermeasures that they have reserved or ordered, but the rate of delivery shall depend on the production capacity of the contractor and on the generally applicable allocation criteria".

[58] Art. 5, §1.

[59] Art. 5, §2.

[60] IDEM, *Explanatory Note on The Joint Procurement Mechanism*, December 2015, p. 1 ff., https://ec.europa.eu/health/sites/health/files/preparedness_response/docs/jpa_explanatory_en.pdf; see also *Flowchart on the implementation of the Joint Procurement Agreement by the different Steering Committees*, https://ec.europa.eu/health/sites/health/files/preparedness_response/docs/jpa_flowchart_implementation_en.pdf.

[61] Art. 4, §2, lett. (a.

[62] Art. 21, §1.

[63] Art. 22.

[64] Articles 27 ff.

[65] Art. 4, §2.

[66] Article 7 establishes Steering Committees' procedures and voting rules.

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Concerning dispute settlement between Contracting Parties, the JPASC is responsible for steering the process necessary to address any lack of compliance with JPA by a Contracting Party and the amicable settlement of disagreements between two or more Contracting Parties. According to Article 40, in the event of a failure to comply by any Contracting Party with JPA, the Contracting Parties will strive to promptly and jointly determine together in the JPASC the means to redress the situation as soon as possible. In the event of a disagreement between two or more Contracting Parties concerning the interpretation or application of this Agreement, the Contracting Parties will use their best endeavours to settle the matter directly. Should this not be possible, any of the Contracting Parties in disagreement may refer the matter to the JPASC, where the Contracting Parties do their utmost to resolve the matter through mediation. If these processes do not remedy the lack of compliance or settle the disagreement, the matter may be referred to the Court of Justice. According to Article 41, any failure to comply with this Agreement, or disagreement about the interpretation or application of this Agreement between the Contracting Parties, i.e., being unresolved within the JPASC, may be brought before the Court of Justice:
(a) by the Contracting Parties concerned, pursuant to Article 272 of the Treaty, where the unresolved matter is outstanding between the Commission and one or more Member States;
(b) by any Contracting Parties concerned that are Member States of the Union, against any other Contracting Parties concerned that are Member States of the Union, pursuant to Article 273 of the Treaty, where the unresolved matter is outstanding between two or more Member States.
The Court of Justice has exclusive jurisdiction to decide upon any failure to comply with this Agreement or disagreement with regard to the interpretation or application of JPA. With regard to the dispute between Contracting Parties and third parties, article 42, §2 "The law applicable to framework or direct contracts pursuant to this Agreement and the competent court for the hearing of disputes under these contracts shall be determined in these contracts".
If the applicable law should be the domestic law of a Contracting Party, any remedy offered by the domestic system can be resorted to. Nevertheless, according to article 4, § 3-4
"the Contracting Parties authorise the Commission to act as their sole representative in instituting or defending any legal proceedings brought by a contractor under a framework contract, except for any legal proceedings brought against a Contracting Party under a specific contract based on a framework contract…The Contracting Parties hereby authorise the Commission to act as their sole representative in bringing any legal proceedings against a contractor under a framework contract, except for any legal proceedings under a specific contract based on a framework contract".

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II.3 Joint Procurement Procedures and Advanced Purchase Agreements during the Covid-19 emergency as a means of speediness, safety, and effectiveness objectives.

During the emergency Covid-19, the JPA showed all its potentialities as well as its limits. Since February 2020, on the JPA basis, the Commission published six tenders and framework contracts have already been signed for individual protection devices; ventilators; laboratory equipment; medicines used in intensive care units, and redeliver, the only medicine with a conditional marketing authorization in the EU for the treatment of Covid-19 patients needing oxygen supply. A tender has been opened for rapid antigen tests. In April 2020, the European Economic Area (EEA) States[67] and six potential candidate countries[68] signed the JPA, bringing the total number of the signatories to 37.

Based on the 'EU vaccine strategy'[69], the Commission has also stipulated the Advanced Purchase Agreements (APA) with individual vaccine producers on behalf of Member States. These agreements are partially different from those signed until now within the JPA because, in return for the right to buy a specified number of vaccine doses in a given timeframe and at a given price, the Commission has financed, through the Emergency Support Instrument[70], a part of the upfront costs faced by vaccines producers. This funding has been considered as a down-payment on the vaccines that have been purchased by the Member States. This approach decreased risks for companies while speeding up and increasing manufacturing. While the JPA attributes to the Commission a role of mere coordination, within the APA framework the Commission invests EU funds in the procedure, even if these funds are used not to purchase vaccine doses but to support and accelerate their invention and experimentation. On 18 June 2020, Commission adopted the Decision approving the agreement with the Member States on procuring Covid-19 vaccines on

[67] The countries that signed the EEA agreement with EC in 1994 are Island, Norway, Liechtenstein.

[68] Liechtenstein, Albania, Montenegro, North Macedonia, Serbia and Bosnia and Herzegovina, Kosovo.

[69] COM (2020) 245 final, 17.06.2020, *EU Strategy for COVID-19 vaccines*.

[70] See Council Regulation (EU) 2016/369 of 15 March 2016 on the provision of emergency support within the Union and Council Regulation (EU) 2020/521 of 14 April 2020 activating the emergency support under Regulation (EU) 2016/369, and amending its provisions taking into account the COVID-19 outbreak, Article 4, §5 «Emergency support under this Regulation may be granted in any of the following forms: (a) joint procurement with Member States as referred to in Article 165(2) of Regulation (EU, Euratom) 2018/1046 whereby Member States may acquire, rent or lease fully the capacities jointly procured; (b) procurement by the Commission on behalf of Member States based on an agreement between the Commission and Member States; (c) procurement by the Commission, as wholesaler, by buying, stocking and reselling or donating supplies and services, including rentals, to Member States or partner organisations selected by the Commission. In the event of a procurement procedure as referred to in point (b) of paragraph 5, the ensuing contracts shall be concluded by either of the following: (a) the Commission, whereby the services or goods are to be rendered or delivered to Member States or to partner organisations selected by the Commission; (b) the participant Member States whereby they are to directly acquire, rent or lease the capacities procured for them by the Commission».

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behalf of the Member States and related procedures[71]. According to the Decision, the Participating Member States, and not the Commission, shall acquire vaccine doses from the manufacturers based on the APAs unless otherwise agreed[72]. All relevant vaccination policies shall therefore remain matters for the Participating Member States. In case a Participating Member State does not agree with the conclusion of an APA containing an obligation to acquire vaccine doses or its terms, it has the right to opt out by explicit notification to the Commission[73]. Once concluded, the terms of the APA shall be legally binding on the Participating Member States, except for those who have exercised their right to opt out[74]. By signing the Agreement, the Participating Member States confirm their participation in the procedure and agree not to launch their own procedures for advance purchase of that vaccine with the same manufacturers (exclusivity clause)[75].

To date, four safe and effective vaccines against COVID-19 have been authorized for use in the EU following positive scientific recommendations by the European Medicines Agency: BioNTech-Pfizer (21 December 2020), Moderna (6 January 2021), Astrezeneca (29 January 2021), and Johnson and Johnson (11 March 2021)[76]. Two other contracts have been concluded that allow the purchase of a vaccine once proven safe and effective: Sanofi-GSK, CureVac[77]. Exploratory talks have been concluded with Novavax and Valneva.

The vaccination campaign started at the end of December 2020 and it is in progress. Contracts published online have a common structure. They establish similar disposals as it concerns procedures, supply and payment conditions, Parties' obligations, and the 'Vaccine Order Form', a template that States have to use for the elaboration of 'specific' contracts. The respect of obligation established by APA (in particular quantities and timing) shall be governed by the law of Belgium and disputes have to be submitted to the courts located in Brussels, Belgium. Problems concerning vaccine transfer, delivery on national territory, and distribution are submitted to the national law. Member States assume the engagement to indemnify the Contractor for any damages, liability, and external legal costs determined by claims arising in connection with the use and deployment of Covid-19 vaccines.

Through instruments such as joint procurements and APA, the Commission tries to assume the role of 'central purchasing bodies', offering States its expertise and

[71] C (2020) 4192 final, 18.6.2020.

[72] Decision (2020) 4192 Annex, Art. 2.

[73] Art. 4.

[74] Art. 5.

[75] Art. 7.

[76] The texts of signed contracts are available at the link: https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/public-health_it#documents.

[77] APA with Curevac, signed on 17 November 2020, is available on line at the link: https://ec.europa.eu/info/sites/info/files/curevac_-_redacted_advance_purchase_agreement_0.pdf

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competences to strengthen their contractual power against suppliers, to assure transparency, procedural speediness, and effectiveness and to avoid competition in supplying between the Member States and their local entities[78].

Considering that the sanitary emergency is generating recurrent production stoppage, restrictions in people and good movements, and, consequently, shorter and more diversified supply chains, JPA and APAs could represent fundamental instruments aimed to assure solidarity and sureness, continuity, and fair distribution of medical goods between States. Since the JPA also involves ESA and potential candidate countries, it could represent a useful cooperation tool besides the EU borders, in a macro-regional dimension.

In the "Proposal for a Regulation of the European Parliament and of the Council on Serious Cross-Border Threats to Health and Repealing Decision No 1082/2013/EU"[79] joint procurements are the object of a deep reform inspired by the APA experience.

Firstly, the Commission and any Member States may engage in a joint procurement procedure conducted pursuant to Article 165(2) of Regulation 2018/1046 of the European Parliament and of the Council "with a view to the advance purchase of medical countermeasures for serious cross-border threats to health". So, advance purchase and risk-sharing between Commission, Member States, and producers become the rule.

Secondly, the exclusivity clause is specifically expressed and generalized[80]. Furthermore, the joint procurement procedure shall allow participation to all Member States, EFTA States, and Union candidate countries[81]. If approved, these reforms would confirm the Commission leadership in medical goods supplying at a macro-regional dimension, with relevant effects in terms of strengthening of contractual power against medical good manufactures, procedure effectiveness and speediness, fighting resource wastes, corruptions, and conflicts of interests.

Reforms of JPA and APA are becoming increasingly urgent in the light of the disputes that have arisen, after the beginning of the vaccine campaign, between the European Commission and vaccine producers as it concerns the timing of supply and delivery of the vaccine doses.

On 26 April 2021, the European Commission launched legal action against AstraZeneca over an alleged breach of contract concerning the delivery of its

[78] G. SDANGANELLI, *Il modello europeo degli acquisti congiunti nella gestione degli eventi rischiosi per la salute pubblica*, in *DPCE on line* 4 (2020) 2323 ff., 2341; E. MCEVOY, D. FERRI, *The Role of Joint Procurement (JPA) during the COVID-19 Pandemic: Assessing its Usefulness and Discussing its Potential to Support a European Health Union*, in *European Journal of Risk Regulation* 11 (2020) 1 ff., 5 ff.

[79] COM (2020) 727 final, 11.11.2020, Art. 12.

[80] See art. 12, §2, lett. c) "Member States, EFTA States and Union candidate countries participating in a joint procurement shall procure the medical countermeasure in question through that procedure and not through other channels, and shall not run parallel negotiation processes for that product".

[81] See art. 12, §2, lett. a).

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coronavirus vaccine. According to the European Commission, AstraZeneca had committed to supplying 180 million doses to the EU in the second quarter of this year but faced multiple delays to shipments[82]. On 18 June 2021, the Brussels competent court, although criticizing AstraZeneca for a serious breach of its contract with the EU after repeated shortfalls, refused to impose a new schedule demanded by the European Commission that would have required the company to deliver 120 million doses by the end of June or pay fines of €10 per dose per day. Instead, the judge ruled that AstraZeneca must deliver only 80.2 million doses by a deadline of Sept. 27. The court is due to hold hearings in September on a second case brought by the Commission seeking judgment on whether AstraZeneca failed in its duty to deliver on the supply contract[83].

The ongoing dispute between the European Commission and AstraZeneca shows that national courts may not be the best solution to the problem concerning the vaccine supply during the pandemic. Indeed, the perspective of only verifying if there was a contract breach could undermine the real purpose that EU and national Institutions should pursue, namely not obtaining damage compensation but receiving timely sure and effective vaccine doses to be administered speedily to their citizens. In this perspective, it could be useful to include in the APA the obligation to try to solve the disputes arising among European Commission, States, and vaccine producers through Alternative Dispute Resolution mechanisms, which, de-conflicting the situation, could help to find a solution able to speed vaccine delivery and distribution, helping the EU countries to rapidly gain the herd immunity necessary to effectively and safely restart socio-economic activities.

3. Conclusions.

In a globalized world, conceiving the issues concerning the provision of public services as a 'domestic jurisdiction' and interpreting them in the classical framework of competence conflicts between Central Government and territorial authorities appears highly reductive.

The Covid-19 emergency underlined the necessity to frame in a multilevel perspective the allocation of responsibilities concerning decision-making, health service organization and management, and procedures. If the Member States have to assure the uniformity of fundamental rights protection, and Regions could better respond to specific territorial exigencies, giving the EU an important coordination role in combatting cross-border health scourges and health threats could assure a more effective and rapid reaction, balance of contrasting Member State interests,

[82] See the Statement released by AstraZeneca on 26 April 2021 available at the link https://www.astrazeneca.com/media-centre/statements/2021/statement-on-eu-legal-action.html.

[83] See F. GUARASCIO, A. SMOUT, *EU loses bid for speedier AstraZeneca vaccine deliveries*, in *Reuters*, 18 June 2021. See also H. KUCHLER, M. PEEL, *EU fails in legal bid to speed up AstraZeneca vaccine supply*, in *Financial Times*, 18 June 2021.

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greater contractual power with medical goods providers, and the application of a spirit of solidarity in the sharing and allocation of resources necessary to overcome the emergency. In this perspective, joint procurement procedures are only an example of procedures that could be better realized if shared between the Member States or coordinated (and funded) at the EU level.

However, increasing EU competences could fail to reach the expected results if it is not matched with a deep reform of the SSN/SSR system aimed to establish not only the limits of the Central Government and Region competences but also the minimum protection standards of the right to health, that has to be assured on the whole national territory and that has to be considered undeniable also in the event of sanitary emergencies.

The next generation programme, REACT EU and the EU4 Health programme could represent a great opportunity to experiment with methods of 'good multilevel governance' in the public health sector, offering significant financial resources both to the Central Government and to the Regions earmarked to pre-defined expense typologies.

It is hoping that the Italian Central Government and Regions will be able to adequately exploit this opportunity, becoming a model also for EU candidates and potential candidates.

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