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HEALTH SOLIDARITY IN PRACTICE: EU COMPETENCES IN THE PHARMACEUTICAL SECTOR

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Abstract: *The pharmaceutical sector highlights the tension between Member State responsibility for healthcare and the growing role of EU regulation. This paper examines the EU´s competences in the pharmaceutical sector de lege lata, focusing on their legal basis and the existing regulatory instruments. It examines relevant provisions of the Treaties and their implications for the role of solidarity in legal basis to adopt regulatory measures in the pharmaceutical sector. The paper further analyses the legal framework governing medicinal products in the EU and explores how the principle of solidarity is reflected in the design and functioning of these regulatory principles. By examining the legal basis and regulatory tools of EU pharmaceutical law, the article aims to assess how solidarity is embedded within the current competence framework of the EU law.*

Key words: *pharmaceutical sector, competences, solidarity, European Union, Covid-19*

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1. INTRODUCTION

No research of any area covered by European Union law can meaningfully begin without answering a fundamental question – what are the competences of the EU and what are the limits and nature of said competences?

The scope and nature of EU´s competences in any area determine the extent of how the EU may regulate a particular field, while simultaneously setting the limits of its legislative and executive action. A clear understanding of EU´s competences is a crucial starting point of any research.

On one hand, this paper aims to examine the competences of the EU in matters within the pharmaceutical sector *de lege lata* and on the other hand aims to explore and analyse the extent to which the principle of solidarity is reflected in the EU´s regulatory instruments that the EU has adopted on the legal basis set out in its competences.

The aforementioned understanding is particularly important in matters regarding the pharmaceutical sector, which acts as a crossover of two seemingly opposite paths: the 'social' path of protecting human health and the economic path, consisting of free

trade.[1]The duality of this sector shapes action taken by the EU and the design of its regulatory instruments. On this background, another question arises – whether and to what extent is the principle of solidarity embedded in those regulatory instruments?

This question is answered primarily via analysis of the existing EU framework regarding the pharmaceutical sector, supplemented by the views of the legal doctrine. Thus, the article is organised as follows:

First, the scope of the EU´s competences in the field of health is analysed, before assessing whether the pharmaceutical sector falls within the scope of (public) health or if it´s regulated on an alternative legal basis, including the conditions on its use. The article further examines the legal basis for key regulatory instruments. Finally, it explores the role of solidarity in the regulation of the pharmaceutical sector in the EU and discusses adopted measures that support solidarity as well as those that undermine it.

2. EU COMPETENCES IN MATTERS OF HEALTH

Whilst discussing EU´s competences, the pharmaceutical sector may appear to fall under the concept of health. At first glance into the articles regarding EU´s competences set in the Treaty on the Functioning of the European Union (hereinafter referred to as ´TFEU´), two different articles (and therefore two different types of EU competences) come to mind: shared competence in the area of common safety concerns in public health matters[2] and the competence to support, coordinate or supplement the actions of the Member States in the area of protection and improvement of human health[3].

What is the difference between these two types of competences and why does it matter?

Shared competence allows the EU to exercise the competence in different ways: it may choose to harmonize national laws, make its own uniform regulations or choose to require mutual recognition[4]. EU´s exercise of its competence limits Member States in taking action in areas falling within the shared competence list – they may take action only to the extent that the Union has not exercised, as stated in Art. 2 (2) TFEU. The EU´s competence to take action to support, coordinate or supplement Member State action is not unlimited: Art. 2 (5) TFEU states that EU´s legally binding acts adopted in areas falling within this competence[5] shall not entail harmonisation of Member States´ regulations. These clarifications answer the question of why the distinction between these types of competences does matter. Each competence determines the extent of harmonisation the EU can partake in.

Pursuant to the aforementioned articles of the TFEU, EU´s competences in the area of (public) health are limited to support, coordinate or supplement the actions taken by the Member States without harmonisation, with one exception falling within shared competence. The exceptions are common safety concerns in public health[6].

Area of public health and its role in the EU law is further specified in Art. 168 TFEU, which sets the EU´s framework, objectives and limits. The first paragraph of this article underlines the aim of the EU to ensure a high-level protection of human health all

[1] Tamara K Hervey, 'EU health law' in Catherine Barnard and Steve Peers (eds), *European Union Law* (4th edn, OUP 2023) 662.
[2] Art. 4 (2) k) TFEU.
[3] Art. 6 a) TFEU.
[4] Paul Craig and Gráinne de Búrca, 'EU LAW: Text, Cases and Materials. UK Version' (7th edn, OUP 2020) 118.
[5] For example, culture or education.
[6] Vincent Delhomme, Emancipating Health from the Internal Market: for a Stronger EU (Legislative) Competence in Public Health' (2020) [11(4)] *European Journal of Risk Regulation,* 748. (accessed on 25.3.2026)

throughout its policies and activities. At the same time, it underscores that Union action shall complement national policies rather than replace them. The limitation of complementing national policies reflects the nature of the public health sector in the Member States. The sector of health services forms a core component of national welfare systems and is one of the larger areas of public expenditure, and therefore Member States (in their role as the masters of the Treaties[7]) are resistant to transfer competences to the EU on a more powerful level[8].

With compliance with Art. 180 and Art. 182 TFEU, the EU also possesses the competence to fund collaborative research into vaccines, treatment, medical devices and equipment, to fund epidemiological research and behavioural research of effective disease containment strategies. The EU competence to fund the abovementioned is certainly connected to the area of health[9].

The EU also affects the health (and pharmaceutical) sector via its competence in competition, set in Art. 3 (1) b) TFEU[10]. Its activity in this sector was increased in 2009, reflecting the Commission´s final report of its Sector Inquiry, which raised awareness of the importance of enforcing the regulation of this sector through competition law.[11] These regulations have significant impact on pricing strategies[12], availability of medicines and nonetheless their innovation.

In order to emphasize the intricate network of competences that *de facto* have an impact on the health sector, another article of the TFEU comes to play: namely Art. 153, which also acts as a legal basis for adopting health norms[13].

As stated in the analysis of EU´s competences above (and also reflected in relevant academic literature[14]), the involvement of the EU in matters of (public) health is not as straightforward as it might appear at a first glance in the Treaty on European Union and the Treaty on the Functioning of the European Union (hereinafter referred to as ´Treaties´). Some authors have rather fittingly named the EU´s involvement in health as a *„patchwork picture of policies"* and emphasized the difficulty of creating comprehensive analysis of this field[15].

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[7] Mária T. Patakyová, Andrej Beleš, Michaela Nosa, Sára Kiššová, Adam Máčaj, Ondrej Blažo and Hana Kováčiková, 'Právo EÚ. Inštitucionálny systém a systém práva' (1st edn, Wolters Kluwer SR s. r. o., 2025) 196.

[8] Anniek de Ruijter, 'EU Health Law & Policy: The Expansion of EU Power in Public Health and Health Care' (OUP 2019) 10.

[9] Kai P. Purnhagen, Anniek de Ruijter, Mark L. Flear, Tamara K. Hervey and Alexia Herwig, ´More Competences than You Knew? The Web of Health Competence for European Union Action in Response to the COVID-19 Outbreak´ (2020) 11(2) *European Journal of Risk Regulation* 297 (CUP) https://doi.org/10.1017/err.2020.35, 299.

[10] Art. 3 (1) b) TFEU follows as: (1) The Union shall have exclusive competence in the following areas: b) the establishing of the competition rules necessary for the functioning of the internal market.

[11] Benoît Durand, ´Competition Law and Pharma: An Economic Perspective´ in Pablo Figueroa and Alejandro Guerrero (eds), *EU Law of Competition and Trade in the Pharmaceutical Sector* (Edward Elgar Publishing 2019) 1.

[12] In this context, it is necessary to point out that the competence of setting the prices of medicinal products or their inclusion in the scope of the national health system or social security schemes falls on the Member States, as stated in Art. 168 (7) TFEU and underlined in Art. 1 Regulation (EC) No 726/2004 of the European Parliament and the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

[13] Giulia Bosi, 'Expanding EU Competence in Health? The need for and Feasibility of Treaty Change' (EU Law Live Weekend Edition No 107, 2022) https://www.iris.sssup.it/retrieve/fd5bbc23-712f-4f64-99b9-2ad94549d6ce/Expanding%20EU%20Competence%20in%20Health.%20The%20Need%20for%20and%20Feasibility%20of%20Treaty%20Change.pdf, 1.

[14] See: De Ruijter (n 8).

[15] See: De Ruijter (n 8).

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The COVID-19 pandemic brought attention to the health and pharmaceutical sector and the EU´s role within. Weaknesses in the existing regulatory framework were discussed, which resulted in calls for a new approach, reflected in different outcomes, such as the Pharmaceutical Strategy for Europe[16] or the Manifesto for a European Health Union[17]. While the Pharmaceutical Strategy for Europe is a Commissions proposal and it is based on the current EU framework, the Manifesto for a European Health Union is an initiative by a former European Commissioner for Health and Food Safety and other professionals, that has found support in NGOs and MEPs[18]. The idea presented in the initiative calls for an amendment of the Treaties, specifically in matters of competence, where it presents an interesting approach. The proposal contains replacement of Art. 4 (2) k) TFEU with „*European Health Union*" and a removal of Art. 6 a) TFEU from the EU´s competence to support, coordinate or supplement. This proposal mirrors the dissatisfaction with the duality of EU´s competence in the health sector.

2.1 DOES THE PHARMACEUTICAL SECTOR NECESSARILY FALL UNDER PUBLIC HEALTH OR IS THERE A (NOT SO) SECRET WEAPON?

At first, the presumption that the pharmaceutical sector is a part of the public health category needs to be addressed. While this statement may seem straightforward and clear, the Court of Justice of the European Union (hereinafter referred to as ´CJEU´) has confirmed in its decisions that the pharmaceutical sector does in fact belong under the term public health. Namely, the CJEU has confirmed the nature of the pharmaceutical sector in decisions *Deutscher Apothekerverband*[19]*, Venturini*[20] and others.

After analysing the EU´s competences in health-related matters, a logical presumption would be that those are the legal basis on which the EU adopts its regulatory framework regarding the pharmaceutical sector. While this statement is not necessarily incorrect, the EU complements its competences in public health by resorting to its powers in the area of internal market, via Art. 114 TFEU. This compensation of EU´s limits to take action is not without complications. There are identifiable problems, such as it undermining the legitimacy of EU health policy, limiting the range of actions that can be adopted and preventing Member States from enacting more protective health measures[21].

The first question that needs to be addressed is how do pharmaceutical products fall within the scope of the internal market? The CJEU has answered this issue in the case *Schumacher*[22], where it confirmed that prohibition of importation of medicines, which were purchased in another Member State is incompatible with EU law. This approach is not controversial, as the sole point of the internal market is removing barriers for products. It is important to note that medicinal products are also tradable products for which a market exists[23].

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[16] European Commission, *´Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Pharmaceutical Strategy for Europe´* COM (2020) 761 final.

[17] European Health Union Initiative, 'Manifesto for a European Health Union' (2020), https://europeanhealthunion.eu/manifesto-page/ (accessed on 2.4.2026).

[18] See n 13, 4.

[19] Joined Cases C-171/07 and C-172/07 *Apothekerkammer des Saarlandes and Others v Saarland* EU:C:2009:316.

[20] Joined Cases C-159/12 to C-161/12 *Venturini v ASL Varese and Others* EU:C:2013:791.

[21] See: Delhomme (n 6).

[22] Case C-215/87 *Heinz Schumacher v Hauptzollamt Frankfurt am Main-Ost* EU:C:1989:111.

[23] See: Delhomme (n 6).

2.2 HOW TO USE THE NOT-SO-SECRET WEAPON?

One of the most important rules of the functioning of the EU is related to the principle of conferral of powers, set in Art. 5 (1) TEU, which means that the EU may only act within the limit that the Member States have set in the Treaties. This principle is relevant in the field of health, because of aforementioned limitations set out in EU´s competences. Consequently, the question of using another article within the conferred competence without the limitations arises and whether there are any conditions of using such article.

The CJEU has answered the question concerning the use of Art. 114 TFEU as a legal basis in matters regarding health in the case *Tobacco advertising*[24]. First, the CJEU has interpreted Art. 168 (5) TFEU (specifically the no-harmonisation provision), meaning that it is not absolutely prohibited to adopt harmonising regulatory instruments that have impact on the protection of public health. It is possible to adopt regulatory instruments which harmonise an area falling within the scope of public health under another legal basis than Art. 168 TFEU, *provided* that it is not used in means of bypassing the no-harmonisation clause.

This is not the only rule of using Art. 114 TFEU (or other articles of the Treaties) as a legal basis. A requirement was interpreted by the CJEU, that the adopted acts must have as its object the improvement of the internal market. This must be a genuine aim of the act, and a sole statement that national regulations are different would be deemed insufficient.

3. LEGAL BASIS AND SOLIDARITY

3.1 LEGAL BASIS OF KEY REGULATORY INSTRUMENTS

The key legal regulatory instruments shaping the pharmaceutical sector are undoubtedly those legislative acts, that are currently a part of the reform set in the Pharmaceutical strategy for Europe.

The Directive 2001/83/ES on the Community code relating to medicinal products for human use[25] lays down definitions of relevant terms, rules on authorisation, mutual recognition, manufacture, distribution, packaging, advertising and pharmacovigilance. The legal basis of this directive is Art. 95 EC (now Art. 114 TFEU). This indicates that the legal act ensures the proper functioning of the internal market.

Another key regulatory instrument in the pharmaceutical sector is Regulation 726/2004, which lays down Community procedures for the authorisation and supervision of medicinal products for human use and establishes a European Medicines Agency[26]. The preamble of his regulation states the same legal basis as the abovementioned directive (so Art. 114 TFEU), with the addition of Art. 152 (4) b) EC (now Art. 168 TFEU). This twofold legal basis shows the dual purpose of the regulation: harmonisation and function of the internal market and the protection of public health within the EU. Notably, Art. 168 TFEU is not listed as a legal basis in the preamble of Directive 2001/83/ES.

[24] Case C- 376/98 *Germany v European Parliament and Council* EU:C:2000:544.
[25] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L 311/67.
[26] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [2004] OJ L 136/1.

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Although the Directive 2001/83/ES and the Regulation 726/2004 are arguably the core regulatory instruments, other EU legislative acts should not be overlooked – namely, Regulation 141/2000 on orphan medicinal products[27] and Regulation 1901/2006 on medicinal products for paediatric use[28]. Both of these regulations were adopted on the legal basis of Art. 95 EC (now Art. 114 TFEU), thereby confirming the dominance of internal market legal basis in pharmaceutical regulation In EU law. This analysis of EU´s choice of legal basis confirms its reliance on internal market competences. A pattern is identified, where the EU adopts regulatory measures based on its competence in internal market rather than its competences in the area of public health, which are limited due to its supporting, coordinating or supplementing nature. Such choice of legal basis points out their main objective, which is to ensure free movement of products between Member States. The regulation of medicines should not be reduced to purely economic consideration, but it should also put significant emphasis on access to safe and effective medicines.

After the Covid19 pandemic, the EU has responded by adopting new regulatory measures. One of these measures is Regulation 2022/123[29] and Regulation 2022/2372[30]. These measures use the principle of solidarity by enhancing coordination between Member States, with the goal of preventing uncoordinated responses to crises that have the potential of fragmenting the set regulation on the sector.

3.2 THE ROLE OF SOLIDARITY IN EU PHARMACEUTICAL REGULATION

The role of solidarity in the EU law is accentuated in Art. 2 TEU, where it is placed among other values on which the EU is founded on. The CJEU has underlined its importance in the case *Opal*[31], where it underlined that while solidarity is explicitly mentioned in the preamble of the TEU, its provisions and the provisions of the TFEU and the Charter of Fundamental Rights of the EU, it is unclear what is its nature and scope. Some provision uses the term "*spirit of solidarity*", while others contain the term "*principle of solidarity*"[32].

An important step in research of solidarity is its conceptual definition. As some authors point out, '*the omnipresence of solidarity in the EU legal order makes it difficult to develop a consistent and generally applicable definition of the concept*'[33]. As stated above, the Treaties themselves seem inconsistent with their use of the term, which only adds to the difficult task of understanding the role of solidarity in the EU law. This has led to an identification of three different dimensions of solidarity: solidarity between Member States; solidarity between Members States and individuals and solidarity between

[27] Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products [2000] OJ L 18/1.

[28] Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 [2006] OJ L 378/1.

[29] Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 20222 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices [2022] OJ L 20/1.

[30] Council Regulation (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level [2022] OJ L 314/64.

[31] Case C-848/19 *Federal Republic of Poland, Republic of Latvia, Republic of Lithuania and European Commission* EU:C:2021:598.

[32] See: (n 31), paras 61-62.

[33]Esin Küçük, 'Solidarity in EU Law: An Elusive Political Statement or a legal Principle with Substance?'(2016) 23(6) Maastricht Journal of European and Comparative Law, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2931741, 40 (accessed on 7.5.2026).

generations[34]. Solidarity in its core may be understood as a collective pursuit and exercise of shared interest.

The understating and interpretation of solidarity in the EU law has remarkably developed throughout the years, which has on one hand added to its complexity, and on the other hand fueled the ambiguousness of the concept. Scholars have identified that solidarity in the EU law is an adaptable concept, ever-changing and shaped by many factors[35], which justifies the author's approach to analyse solidarity through the regulatory framework of the pharmaceutical sector regulation.

Regarding provision of the TFEU where the term solidarity is explicitly used, as stated in the analysis of the EU´s competences above, the area of public health and the role of the EU in support, coordination and complementing is regulated in the Art. 168 TFEU. This provision lacks an explicit articulation of the principle of solidarity, in contrast to Art. 80 TFEU for example, where the term is used. Even if not explicitly stated, Art. 168 does lay down some requirements on solidarity in actions taken based on this article. In (2) it states that the Member States coordinate their policies with cooperation with the Commission for the purpose of ensuring a high level of the protection of public health. An aspect of solidarity is also expressed in (1), via references to monitoring and combating serious cross-border health threats. Despite the lack of explicit articulation of the principle of solidarity in the wording of Art. 168 TFEU, the individual elements of the principle of solidarity embedded in the wording demonstrate that the functioning of the area of public health within the EU is based on collective action a mutual interdependence.

The same interpretative approach can be applied to Art. 114 TFEU, which (as previously mentioned) serves as a predominant legal basis in the regulation of the pharmaceutical sector. Art. 114 TFEU also does not explicitly refer to the term solidarity, similarly as Art. 168 TFEU, some of its provisions reflect elements of solidarity. The implicit indication of coordination, mutual responsiveness and shared responsibility between the EU and Members States stemming from the obligation to ensure a high level of protection of health (set in Art. 114 (3) TFEU) is in its core an embodiment of solidarity within the internal market framework.

The search for an explicit reference to the term solidarity or the principle of solidarity within the regulatory framework of the pharmaceutical sector proves to be challenging, as the use of the term can be identified as fragmented rather than systematic. Analysing the four regulatory measures, the term is not used explicitly once in either of them, further confirming the observation.

So where can one come across an explicit reference to solidarity in measures regulating the pharmaceutical sector? Regulation 2022/123, which was adopted after the pandemic, uses the term solidarity in its recital, where it refers to solidarity as means of enhancing resilience and strengthening crisis management and preparedness. Solidarity is therefore put into a role of an instruments aimed to navigate coordination and collective action between the Member States. The aim of the Regulation 2022/123 is to reinforce the role of the European Medicines Agency (hereinafter referred to as ´EMA´) in

[34] Peter Hilpold, 'Understanding Solidarity within EU Law: An Analysis of the „Islands of Solidarity" with Particular Regard to Monetary Union' (2015) Yearbook of European Law 34, https://soeulaw.jus.unipi.it/wp-content/uploads/2020/01/P.-Hilpold-Understanding-Solidarity-within-EU-Law-An-Analysis-of-the-Islands-of-Solidarity-with-Particular-Regard-to-Monetary-Union.pdf , 259. (accessed 8.5.2026).

[35] Esin Küçük, 'Solidarity in the EU: What Is In a Name?' (2023) 6(2) Nordic Journal of European Law 23, https://doi.org/10.36969/njel.v6i2.25409, (accessed on 9.5.2026).

events of medicine shortages, crises and emergencies[36] Under provisions of this regulation EMA has developed a voluntarily solidarity mechanism, aimed to coordinate Member States assisting each other in cases of medicines shortages. This explicit appearance of solidarity show that within the EU´s pharmaceutical regulation it can act as a governance tool, not just a general principle.

Another EU regulatory measure, adopted in the aftermath of the Covid19 pandemic, explicitly references solidarity. Regulation 2022/2371[37] emphasizes in its recital that serious cross border health threats require a coordinated approach based on solidarity and responsibility. Solidarity is once again reflected in a mechanism of joint procurement of medical countermeasures[38].

As stated above, the four key regulatory measures do not explicitly reference the term solidarity nor the principle of solidarity, but that does not mean it is not implicitly embedded in their structure and objectives. These regulations and a directive regulate authorisation procedures of medicines, which are coordinated, as well as mutual recognition of authorisation mechanism[39]. The principle of solidarity is also embedded in the obligation of sharing information between the Member States via EudraVigilance, set in the Regulation 726/2004[40]. The pharmacovigilance system enables access and exchange of safety data between Member States, to support coordinated responses to risks related to medicinal products.

The entirety of the EU pharmaceutical regulation framework is built on the mechanism of mutual assistance, cooperation between the Members States, aimed to ensure availability, accessibility of medicines. This mechanism could not work without a requirement of a certain degree of solidarity embedded in the cooperation. This gives solidarity the role of being a functional core of the regulation, even though it is not expressly labelled as such.

The role of solidarity after the Covid19 pandemic has been emphasized by academics, as it revealed that lack of coordination between Member States can undermine the principle and therefore disrupt the functioning of the internal market[41]. As the author has pointed out, the EU has had a tendency to take action in the pharmaceutical sector via internal market integration and act as a regulator. The limits of the EU´s regulation have been exposed by the pandemic and the cross-border crises it caused, which contributed to the need of stronger Member States coordination and solidarity-based mechanisms within the EU framework[42].

[36] European Medicines Agency, 'EMA takes further steps to address critical shortages of medicines in the EU' (2023) https://www.ema.europa.eu/en/news/ema-takes-further-steps-address-critical-shortages-medicines-eu (accessed 5.4.2026).
[37] Regulation (EU) 2022/2371 on the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2012/EU [2022] OJ L 314/26.
[38] Susanna Villani, 'Perspectives of Solidarity within the EU Legal Order in the Time, of the COVID-19 Pandemic' (2023) 4(1) Yearbook of International Disaster Law Online 81 https://doi.org/10.1163/26662531_00401_006, (accessed on 5.5.2026).
[39] See: (n 25) Art. 27-39.
[40] See: (n 26) Art. 24.
[41] Marco Cavaleri, Fergus Sweeney, Rosa Gonzalez-Quevedo and Melanie Carr, 'Shaping EU medicines regulation in the post COVID-19 era' (The Lancet Regional Health- Europe, V9, 2021) https://www.thelancet.com/pdfs/journals/lanepe/PIIS2666-7762(21)00169-1.pdf (accessed 10.4.2026).
[42] Anniek de Ruijter, Tamara Hervey and Barbara Prainsack, 'Solidarity and Trust in European Union Health Governance: Three Ways Forward' (2024) The Lancet Regional – Europe 101047, 3. https://doi.org/10.1016/j.lanepe.2024.101047 (accessed on 9.5.2026).

4. EU MEASURES SUPPORTING AND UNDERMINING HEALTH SOLIDARITY

The EU has adopted many measures within the area of health. Through analysing these measures, it can be identified that solidarity embedded in them may act as a double-edged sword: by either supporting joint action or undermining health equity.

4.1 REGULATORY INSTRUMENTS SUPPORTING HEALTH SOLIDARITY

While talking about solidarity within the sector of pharmaceuticals, one of the main instruments supporting solidarity is the joint procurement of medical countermeasures in Regulation 2022/2371. This instrument supports solidarity within the sector by enabling Commission and any Member State to make a joint purchase of medical countermeasures, which strengthens bargaining power against pharmaceutical companies a thereby ensures access to medicines regardless of Member State´s market size. This *sui generis* legal instrument[43] brings solidarity into practice by enabling coordination of public purchases to avoid duplication of procurement procedures at national level and competition between buyers[44]. This mechanism combines Member States 'purchasing power and directs medical supplies where they are needed in times of urgency. It's important to point out that the join procurement of medical countermeasures by the means of Regulation 2022/2371 is to be used for *„advance purchase … in anticipation of serious cross-border threat to health*" and is open to not only EU Member States, but also EFTA Member States, EU candidate countries and countries such as Vatican City and or Andorra[45].[46] The option for non-EU states to participate in this mechanism leads to concrete framework that operationalizes health solidarity beyond Union borders. While this mechanism of joint procurement is meant to be used in advance of a health crisis, there are other mechanisms of joint procurement in the health and medical field on the EU level. There are also other joint procurement mechanisms such as Regulation 2016/369 [47] or Regulation 2021/522[48], which in contrast to joint procurement of medical countermeasures by Regulation 2022/2371 require either a formal establishment of a public health emergency or a formal decision on their activation before their use.[49] Although these mechanisms require a formal trigger and can only be used during a declared health crisis, they represent a high degree of EU solidarity in funding and distributing medical supplies to affected Member States.

Another measure supporting solidarity in the pharmaceutical sector at the EU level, although voluntary, is the Regulation 2022/123, which supports solidarity by

[43] Emma McEvoy and Delia Ferri, 'The Role of Joint Procurement Agreement (JPA) during the COVID-19 Pandemic: Assessing its Usefulness and Discussing its Potential to Support a European Health Union' (2020) 11(4) European Journal of Risk Regulation, 6. https://doi.org/10.1017/err.2020.91 (accessed on 17.8.2026).
[44] Albert Sanchez-Graells, 'Procurement in the time of COIVD-19' (2020) 71(1) Northern Ireland Legal Quarterly, 84. https://doi.org/10.53386/nilq.v71i1.531 (accessed on 17.8.2026)
[45] As of August 2026, the Joint Procurement Agreement to procure medical counter measures is signed by 39 countries. Source: European Commission, ´Signing ceremonies for Joint Procurement Agreement´ Public Health. https://health.ec.europa.eu/health-security-and-infectious-diseases/crisis-management/signing-ceremonies-joint-procurement-agreement_en (accessed on 19.8.2026).
[46] Katharina Ewert, 'EU Joint Procurement – An Overview' (April 8, 2025) Inside EU Life Sciences. https://www.insideeulifesciences.com/2025/04/08/eu-joint-procurement-an-overview/ (accessed 20.8.2026)
[47] Council Regulation (EU) 2016/369 of 15 March 2016 on the provision of emergency support within the Union [2016] OJ L 70/1.
[48] Council 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, and repealing Regulation (EU) No 282/2014 [2021] OJ L 107/1.
[49] See: Ewert (n 46).

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enabling Member States to request assistance from another Member State during a medicine shortage. The use of this mechanism is conditional on the Member State in crisis not being able to resolve its shortage of an essential pharmaceutical product via its own national mitigation. In such case other Member States participating in this mechanism can redistribute their own stock of missing pharmaceutical products to help prevent localized public health crisis. It's important to point out that this solidarity mechanism has its own safeguards. The request under this framework can be initiated only as a last resort, after the affected Member States has exhausted all options on their national level[50] – either redistribution of said medicine across its territory or using alternatives.

A measure supporting solidarity and cooperation is the joint clinical assessments established by Regulation 2021/2282[51]. This mechanism enables Member States to pool and share knowledge on medicinal products. Such system allows Member States to reduce duplicate clinical assessments. With lesser need to use scientific resources or even less administrative burden, it's simpler to assess innovative medicines quicker. This possibility leads to a more flexible adapting of new medicines to Members States market and therefore reducing differences across the EU. As of 2026, the joint clinical assessments is in force for oncology products and in 2030 will be in force for all products.[52]

4.2 PRACTICES THAT MAY UNDERMINE SOLIDARITY IN THE EU PHARMACEUTICAL SECTOR

While the EU framework analysed above incorporates measures created with solidarity in mind, whether explicitly or implicitly, the Union has not created any mechanisms with the objective of undermining solidarity. Nevertheless, it is possible to identify some mechanisms and practices that in practice undermine solidarity in the pharmaceutical sector. One of these practices is embedded in the core of internal market – in the free movement of goods. Exercising this Treaty protected right, parallel traders buy pharmaceuticals at lower prices in lower price Member States and export them to other markets at higher prices, with the intention of maximizing profit. This practice is not in itself harmful or illegal, but it can have different effects. Patients in importing Member State may benefit from lower price of pharmaceutical product and on the other hand exporting Member State may face problems with stock and low medicine prices in a Member State may have the consequence of manufacturers delaying the launch of new medicines in that market.[53] A mechanism that in practice undermines solidarity is the fragmentation of pricing of pharmaceutical measures. As explicitly stated in regulation 726/2004[54], the pricing of medicines and their inclusion in national health insurance systems remain strictly within the competence of each Member State. This makes access to healthcare dependent on Member States´ wealth. A possible result may be an incentive for pharmaceutical companies to delay launching new medicines in lower

[50] European Medicines Agency 'MSSG Voluntary Solidarity Mechanism' (2025) EMA/323326/2023, Rev. 1. 2. (accessed 26.8.2026).
[51] Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU
[52] Mondher Toumi et al, 'The European Union´s Health Technology Assessment Regulation (EU-HTA R) Will Prosper Despite Major Setbacks' (3 August 2026) 14(3) Journal of Market Access & Health Policy, 2. https://doi.org/10.3390/jmahp14030045 (accessed on 20.8.2026).
[53] Fabio Pammolli and Armando Rungi, 'Access to Medicines and European Market Integration' (2016) IMT Lucca EIC Working Paper Series 01/2016, 17. http://dx.doi.org/10.2139/ssrn.2717501 (accessed 20.8.2026)
[54] Art. 1

income Member States to protect higher prices in wealthier markets, and lead to unequal access to medicines across the EU[55] and therefore undermining cross-border solidarity between Member States in the sector.

5. CONCLUSION

The aim of this paper was to examine the nature and scope of the EU´s competences in the pharmaceutical sector and to analyse how the principle of solidarity is reflected within the current existing regulatory framework.

The analysis has shown that the EU´s competences in this sector are two different pathways. Public health remains primarily in the domain of the Member States, and the EU has developed regulatory framework affecting the pharmaceutical sector via its competences in the internal market. The extensiveness of the EU´s use of Art. 114 TFEU as legal basis on which it adopts regulative measures is seen in the set example of chosen regulatory instruments, which the authors considers as key within the sector. The choice of a legal basis is reflected in the mechanisms and objectives set in those instruments. Free movement of pharmaceuticals and medicinal products are the primary functional basis of these regulations and directives, while public health sits seemingly in the background. This underlines the duality of the pharmaceutical sector, where economic interests and the protection of public health cross.

For the purposes of this paper, solidarity is understood in a broad sense. It refers to the collective pursuit of shared interests related to public health via coordinating information exchange, joint mechanisms and assistance between Member States.

Based on the analysis of the EU´s competences, the paper furthermore examines the role of solidarity within the regulatory framework. It demonstrates that solidarity is not systematically embedded explicitly in the legislative framework. Its explicit reference is absent even in the relevant provisions of primary law: Art. 168 and Art. 114 TFEU. Nevertheless, these provisions contain individual elements of solidarity, implicitly woven through the text and reflecting the Union´s reliance on (and the importance of) coordination and mutual responsiveness in the collective pursuit for both the protection of public health and functioning of the internal market. The paper demonstrates that solidarity as a principle of EU law is not embedded in the legal framework regarding the pharmaceutical sector systematically, nor is it embedded explicitly throughout the regulatory measures, subject to few exceptions. Rather than explicitly, solidarity in the health and pharmaceutical sector operates implicitly, through created mechanism ensuring coordination, joint action and information exchange between the Member States. A change is noticeable in regulations adopted after the Covid19 pandemic, where solidarity is becoming a practical tool used in the pharmaceutical sector, as can be seen in crisis coordination and joint procurement.

Crucial is the practical realization of solidarity in the sector. Created mechanisms actively strengthen collective powers in price negotiation and supply distribution, while internal market dynamics unintentionally undermine the effort of cross-border solidarity in the pharmaceutical sector. Solidarity in the EU pharmaceutical sector therefore remains in a constant tension between market integration and the aim of equal protection of public health.

[55] See: Pammolli and Rungi (n 53) 17.

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