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Using Q-Methodology to study Concurrent Policy Change in the EU: The Emergence of the European Health Union

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Introduction

Policy process research has traditionally focused on testing and refining theories and frameworks through their application to individual instances of structural policy change—typically a single marquee reform or a package of reforms addressing an identified issue that reconfigures the goals and means of public policymaking (Weible, 2023; Hall, 1993). However, comparatively less attention has been paid to the study of concurrent instances of policy change within a sector—often addressing different policy challenges—and to the ways in which their interaction shapes actor dynamics and policy priorities. This paper contributes to addressing this challenge by combining a modified iteration of the Multiple Streams Framework tailored to the EU level—the EU-MSF—with an innovative application of Q-Methodology, a systematic approach to correlating individuals' viewpoints through non-traditional factor analysis, to study the emergence of the European Health Union.

The European Health Union refers to the EU's consolidated health policy response to the COVID-19 pandemic, as articulated and advanced by EU policymakers since 2020 (von der Leyen, 2020). The European Health Union policy programme comprises both initiatives designed and adopted in the immediate aftermath of the pandemic's outbreak—most notably the establishment of the EU Health Emergency Preparedness and Response Authority (HERA)¹, the extension of the European Medicines Agency's (EMA) mandate to include shortages monitoring², and the adoption of the Serious Cross-Border Health Threats Regulation³—as well as instances of structural policy change that were initiated prior to the pandemic but were finalised during or shortly after the pandemic period, most prominently the revision of the General Pharmaceutical Legislation (Council of the European Union, 2025) and the establishment of the EU Health Technology Assessment (HTA) framework⁴. The former represents the first comprehensive overhaul in over two decades of the EU's rules governing the approval of innovative medicines in the single market, alongside the associated incentive structures for manufacturers. The latter concerns the creation of an EU-level institutional framework for assessing the added value of new health technologies, including a system of Joint Clinical Assessments (JCAs), following three decades of voluntary cooperation.

Therefore, the European Health Union provides a fitting case study through which to answer:

How do policy stakeholder preferences across concurrent policy agendas shape policy outputs and the overarching value orientation of a policy sector? And how does crisis affect this process?

Answering these questions requires, first, the measurement of policy preferences across and between concurrent reform agendas; second, the integration of this assessment within a sector-level policy process

¹ Commission Decision 2021/C 393 I/02

² Regulation (EU) 2022/123

³ Regulation (EU) 2022/2371

⁴ Regulation (EU) 2021/2282

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analysis; and third, the evaluation of both the short- and longer-term impacts of crisis on the evolution of policy goals and priorities.

As such, this paper is structured as follows. First, it provides an overview of EU-level policy process research, before introducing the EU-MSF as the overarching analytical framework of the study. It then introduces Q-Methodology, detailing its administration, data processing, and integration into the analysis. Next, the EU-MSF is applied to the study of the concurrent policy agendas comprising the European Health Union, with particular emphasis on leveraging Q-Methodology within the policy stream to measure the relative prioritisation of issues, policy network integration, and value acceptability across reforms. Finally, the findings are discussed in light of the research questions, and the conclusions draw out implications for policy process research, EU studies, and scholarship on crisis politics and health policy.

The study concludes the COVID-19 pandemic tested the sustainability of Member States' health systems, exposed inequalities in health outcomes across EU patients, and scrutinised the institutional capacity of the EU pharmaceutical policy sector across both pharmaceutical and public health functions. Crucially, the nature of the crisis as a public health emergency allowed long-standing problems facing the sector to surface simultaneously, underscoring their interconnectedness while constraining framing contests.

In the face of this problem-driven window of opportunity, policy actors found favourable conditions to advance both new and ongoing policy agendas. However, even as these reform processes unfolded concurrently within the sector, stakeholders exhibited markedly different patterns of prioritisation across them, generally attributing greater significance to agendas that had been initiated prior to the COVID-19 outbreak. Across reforms, the analysis highlights that EU pharmaceutical policy stakeholders have coalesced around three overarching policy viewpoints: one most strongly articulated by supranational institutions and policy instruments, one most prominently expressed by patients' associations, and one most clearly associated with the pharmaceutical innovation industry.

At the same time, the sector has experienced a clear shift in its prevailing value orientation, towards the pursuit of health-oriented rather than single-market-focused policy outcomes. This shift has been driven by changes in value acceptability following the widespread surfacing of health and public health challenges under pandemic conditions and reinforced by narrative convergence around health security and resilience. In this sense, the European Health Union can be understood as an extension of pandemic-generated momentum into the post-pandemic period.

Beyond its empirical findings, the study demonstrates how the EU-MSF can support robust EU-level policy process research at both the programme and sectoral levels and introduces methodological innovations using Q-Methodology to generate systematic metrics for key policy process variables.

EU-level Policy Process Research and the EU-MSF

The application of policy process tools to the EU has been considerably more limited than in national settings (Karokis-Mavrikos, 2025b; Ackrill et al., 2013). The EU's historically hard-to-define status—occupying a grey area between an international organisation and a polity—has instead motivated the development of a distinct body of scholarship explaining its evolution by combining insights from political

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science and international relations: the theories of European integration. Over time, Neofunctionalist (Haas, 1958; Schmitter, 2005), Liberal Intergovernmentalist (Moravcsik, 1998), Postfunctionalist (Hooghe & Marks, 2009; Marks et al., 1996), and related accounts (see also Pierson, 1996; Burgess, 2000; Risse, 2009) have offered alternative explanations for the transfer of competencies to EU institutions, primarily focusing on the Union's supranational governance architecture.

Nevertheless, while this body of scholarship has been successful in explaining the EU's macro-political evolution across successive Treaty revisions, it has more limited analytical capacity to capture the drivers of structural policy reform within the EU's contemporary institutional landscape. In recent years—particularly since the Treaty of Lisbon (2009)—scholars have increasingly converged on viewing the EU as a *sui generis* political system (Hix & Høyland, 2011), in which structural policy change primarily takes place through the Ordinary Legislative Procedure (OLP). As a result, it has been argued that shifting the analytical focus from the macro to the meso level, alongside a greater emphasis on policy process dynamics, provides a more comprehensive foundation for understanding contemporary EU-level policy change—much as in national political systems (Zahariadis, 2013). To this end, scholars have increasingly sought to extend and adapt policy process frameworks to the EU context (e.g. von Malmborg, 2023; Brooks, 2018; Benson & Russell, 2015; Princen, 2013; Citi, 2013).

Among these efforts, the literature on the Multiple Streams Framework (MSF) arguably constitutes the most promising body of research to date. The MSF builds on the “garbage can model” of organisational choice (Cohen, March, & Olsen, 1972) to analyse policymaking under conditions of ambiguity—that is, situations in which multiple interpretations of the same circumstances coexist (Kingdon, 1984; Zahariadis et al., 2023). The EU's political system has repeatedly been characterised as “an emerging garbage can” (Richardson, 2001), “an obvious candidate” for garbage can analysis (Olsen, 2001), and a “loosely coupled system” (Weick, 2001), exhibiting fluidity in stakeholder participation, opacity in organisational capacity, dynamic actor preferences, and high procedural complexity.

As such, Zahariadis (2008), Ackrill et al. (2013), and Exadaktylos (2023) have emphasised the theoretical transferability of the MSF to the EU level, while Borrás and Radaelli (2011), Bache (2012), Goyal et al. (2021), and Herweg (2016) have presented applications of the MSF—or elements of the framework—to EU-level case studies, often in combination with other theories. However, for MSF research to move beyond isolated applications and develop into a policy process framework capable of explaining EU policy change across issue areas, a systematic programme of theory building and empirical testing is required.

Seeking to address this challenge, Karokis-Mavrikos (2025a; 2025b) has introduced the EU-MSF, a comprehensive adaptation of the Multiple Streams Framework to the contemporary configuration of the EU political system. The EU-MSF retains the MSF's core hypothesis and structural components: *policy outcomes result from policy entrepreneurs successfully exploiting windows of opportunity to couple three independent and ever-flowing streams—problems, policies, and politics—through strategic action*. However, necessary adaptations are introduced where functional equivalents of the MSF's variables cannot be readily identified within the EU political system.

Specifically, within the problem stream, given the EU's multi-level governance architecture spanning national and supranational levels, the direction of indicators and policy feedback—that is, where signals

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originate and where they are directed—is identified as a key determinant of the timing and scope of attention mobilisation. Within the policy stream, levels of policy network integration are identified as shaping both the nature of favourable policy alternatives, in terms of value acceptability and technical feasibility, and the effectiveness of policy entrepreneurship strategies in advancing structural reform. Finally, within the politics stream, a more far-reaching adaptation is introduced to account for the comparatively weaker impact of turnover in the European Parliament or changes in European Commission personnel on shifts in political momentum. Instead, drawing on the highly structured nature of EU decision-making, it is proposed that political narratives articulated by the three EU institutions participating in the Ordinary Legislative Procedure (OLP)—the European Commission, the European Parliament, and the Council of the European Union—provide a more informative indicator of political momentum.

Specifically, the European Commission is expected to promote a 'functional' conception of the EU public, prioritising technocratic expertise, process simplification, and the reduction of transaction costs. By contrast, the European Parliament is expected to embody a 'popular' conception of the EU public, emphasising democratic accountability and the mitigation of social, political, and economic inequalities. Finally, the Council is expected to express a 'ruling' conception of the EU public, conflating national public preferences with national interests as articulated by government representatives and prioritising national strengthening through monetary and regulatory benefits. On this basis, political willingness for EU-level policy change is assessed through the degree of compatibility between policy alternatives and institutionally narratives.

Research Design

This study combines the EU-MSF with an innovative application of Q-Methodology, complemented by elite interviews and document analysis, to examine policy change across concurrent policy agendas in the EU pharmaceutical policy sector. Emphasis is placed primarily on the policy stream and, secondarily, on the politics stream of the EU-MSF. In the former, the analysis introduces methodological innovations through Q-Methodology to systematically evaluate policy network integration, the value acceptability of policy alternatives, and shifts in value orientation at the sectoral level. In the latter, the short- versus long-term dimensions of political narratives are examined in order to assess the impact of crisis on political momentum across concurrent reform processes.

Q-Methodology was originally developed by William Stephenson in the 1930s as a systematic approach to studying human subjectivity, combining psychological principles with statistical techniques. It identifies operant subjectivity by employing non-traditional factor analysis to correlate research subjects on the basis of their viewpoints (Herrington & Coogan, 2011; Brown et al., 2008). Over time, the application of Q-Methodology has expanded across a range of disciplines, including education, where it has been used to examine teachers' attitudes and students' learning preferences (Atkinson, 2004; Watts & Stenner, 2012); communication and media studies, to analyse audience perceptions and media consumption patterns (Ockwell et al., 2009); and environmental studies, to assess public attitudes towards sustainability (Webler et al., 2009). In public policy, a more limited body of work has employed Q-Methodology to

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evaluate policy actors' viewpoints, including studies of participants in European Commission committees (O'Connor, 2013).

Q-Methodology begins with the construction of a *Concourse*: a set of possible statements that individuals have made or could make about a given topic, covering a comprehensive range of viewpoints (Van Exel & De Graaf, 2005). The concourse then informs the development of a *Q-set* (or Q-sample), a subset of the concourse typically comprising between 30 and 50 statements. The Q-set consists of statements selected for their particular relevance to the study and is designed, as a whole, to be representative of the range of themes and perspectives contained within the concourse.

For the construction of the concourse and Q-set, this study drew on 20 elite interviews and more than 300 policy documents, including binding and non-binding EU acts; inputs to the EU policy process (e.g. impact assessments and consultation contributions); and publications by non-institutional stakeholders (e.g. position papers and press releases) and international organisations (e.g. the WHO). The final Q-set comprised 30 statements, proportionally divided across the three policy reform agendas examined in the study. One-third of the statements addressed the revision of the General Pharmaceutical Legislation, one-third focused on the new EU HTA framework, and the remainder concerned pandemic-response initiatives and the post-crisis configuration of the sector. Selected statements closely reflected official policy and organisational positions, enabling the data processing stage to assess the degree of alignment between stakeholder preferences and policy-oriented outputs. A shuffled version of the Q-set along with a breakdown of statements by policy area, is provided in Appendix Table 1.

The Q-set was then presented to a set of participants (the *P-Set*). The literature identifies P-sets of between 12 and 36 individuals as ideal, selected through purposive sampling based on participants' expertise on the topic and the heterogeneity of their viewpoints (Webler et al., 2009). In this study, a P-set of 15 participants was constructed, ensuring representation across key institutional and non-institutional actors involved in EU pharmaceutical policymaking across the reform agendas under study (Table 1). This includes representatives from the EU's three decision-making institutions—the European Commission, the European Parliament, and the European Council—drawn from the relevant health and pharmaceutical policy divisions; the key EU bodies responsible for pharmaceutical authorisation and health technology assessment (the EMA and EUnetHTA); and representatives from the EU's two dominant categories of interest stakeholders: the pharmaceutical innovation industry and patients.

Table 1: Distribution of Q-Methodology Participants by Organisational Affiliation

Affiliation	Number of Participants
European Commission (DG SANTE and DG HERA)	3
Patients' Associations	3
Associations of Pharmaceutical Manufacturers	3
European Parliament	2

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European Council	2
European Medicines Agency (EMA)	1
EUnetHTA	1

Table 1: Distribution of Q-Methodology Participants by Organisational Affiliation

Participants were asked to rank the 30 statements using the Q-Grid illustrated in Figure 1 with responses ranging from -3 (“least likely to reflect my policy viewpoint”) to 3 (“most likely to reflect my policy viewpoint”). A neutral position (0) indicated comparative indifference, and the sorting followed a forced distribution format, requiring participant rankings to align with the intended bell curve structure. Additionally, participants were asked to elaborate on their rankings both during and after the exercise, providing supplementary interview-type data. The exercise was administered between March and June 2023.

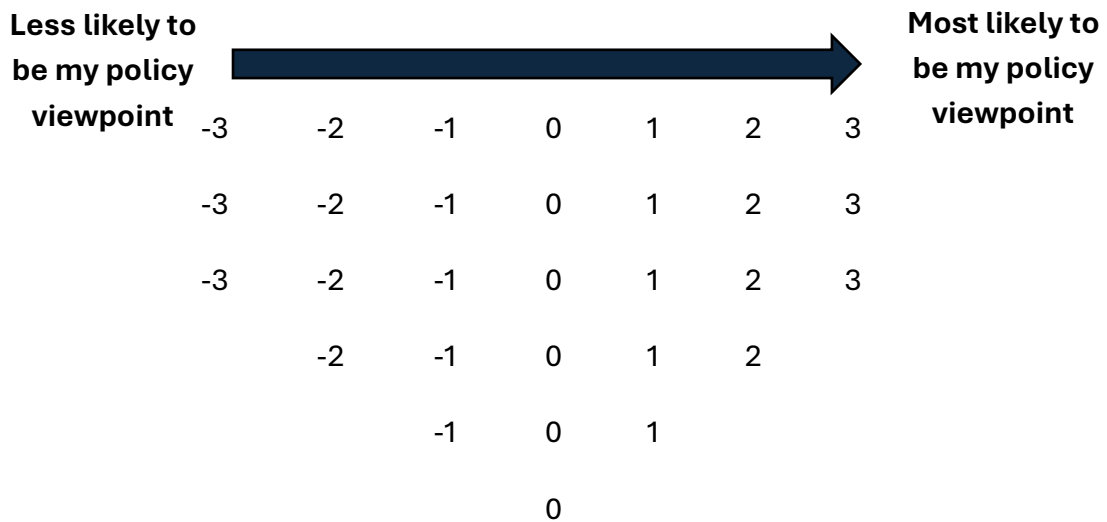


Figure 1: The Q-Grid

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The collected data comprised fifteen individual Q-sorts—rankings of the Q-set statements according to the Q-grid. Cross-correlations between participants' Q-sorts are presented in Appendix Table 2. To interpret these correlations and identify clusters of similarity in participants' policy viewpoints, Centroid Factor Analysis (CFA) was employed. CFA is the preferred factor extraction method in Q-methodology, as it preserves differences between respondents' perspectives rather than smoothing them out, thereby emphasising distinctive viewpoints. CFA was paired with Varimax rotation to minimise cross-loadings and ensure that respondents were unambiguously assigned to the factor that most closely reflects their policy viewpoint. An optimal number of three factors was identified following an evaluation of eigenvalues⁵—that is, the proportion of total variance explained by each factor (Appendix Figure 1).

Participants were assigned to one of the three factors based on their dominant factor loading. All participant Q-sorts loading on each factor were then combined to calculate factor-specific standardised scores (Z-scores) for each statement. This process involved weighting each participant's contribution by the magnitude of their factor loading and dividing the sum of weighted scores for each statement by the sum of factor loadings. The resulting Z-scores were subsequently converted into factor arrays—that is, idealised Q-sorts representing each of the three factors (or viewpoints)—in accordance with the Q-grid. For example, the three statements with the lowest Z-scores were assigned to the “-3” slots, the next four lowest to the “-2” slots, and so forth. Appendix Table 3 presents the idealised collective score (factor array) for each statement across the three factors. Finally, drawing on z-scores, statements were assessed to determine whether they reflected a consensus outlook across factors or whether the positions expressed by one or more factors were distinguishing⁶.

The Q-Methodology outputs are incorporated into the EU-MSF analysis, primarily within the policy stream, and are complemented by the primary data collected through document analysis and elite interviews, particularly within the problem stream. Interviewees are listed with their affiliation to preserve anonymity.

⁵ According to the Kaiser criterion (Yeomans & Golder, 1982), eigenvalues greater than 1 are considered meaningful, as they explain more variance than an individual Q-sort. In identifying the maximum meaningful number of viewpoint clusters, the optimal number of factors is determined by those meeting the Kaiser criterion (>1) before the eigenvalue plot—the scree plot—levels off.

⁶ Pairwise comparisons between factors for a given statement can determine whether the absolute difference in factor z-scores is larger than the standard error of differences. Where all pairwise comparisons between factors for a given statement are significantly different at p-value < 0.05, the statement is defined as “distinguishing” for all factors. Where only the comparisons of a given factor with all other factors are significant at p-value < 0.05 – and the comparisons between all other factors are not significant – the statement is labelled as “distinguishing” for the given factor. When none of the comparisons are significantly different, the statement is labeled as “consensus”.

The Problem Stream

For the EU, the outbreak of the COVID-19 pandemic in early 2020 marked an instance of a systemic focusing event. As proposed by the EU-MSF, “focusing events at the EU level are defined as unpredictable shocks with harmful impact on the functioning of polities, that may extend from the national to the international level, but which are abruptly and simultaneously recognised by most participants in one or more EU policy subsystems” (Karokis-Mavrikos, 2025a; Birkland, 1998).

As a public health emergency, the COVID-19 pandemic intrinsically drove the rapid surfacing of problems across policy sectors. However, in the EU pharmaceutical policy sector in particular, the pandemic had a disproportionately higher impact in bringing challenges to light. On the one hand, medical countermeasures—such as antiviral medicines, vaccines, and diagnostic technologies—remain society's primary instruments for combating viral outbreaks. On the other hand, pharmaceutical products occupy a distinctive position in the EU, functioning simultaneously as single market goods and as health policy instruments. While health policy remains predominantly the responsibility of EU Member State authorities, safeguarded by the principle of subsidiarity⁷, single market regulation falls under EU supranational competence. As a result, pharmaceutical policy has frequently served as the EU's principal channel for pursuing health-related policy objectives (Permanand and Mossialos, 2005).

In this context, two categories of problems monopolised the attention of EU pharmaceutical policy stakeholders following the COVID-19 outbreak, resurfacing long-standing challenges in the process.

Health Systems' Fragility and Health Outcomes Inequalities

First, the virus's rapid transmission and high fatality rates (Hu et al., 2021), combined with limited scientific knowledge on infection management, placed the resource sustainability of Member State health systems under unprecedented scrutiny. “The Italian experience highlighted the fragility of national health systems and the magnitude of regional and economic inequalities regarding access to healthcare in extreme fashion. While we were scrambling to understand what this new virus was all about (COVID-19), thousands of Italians were scrambling for hospital beds and carers; that is in a founding EU Member State with free universal healthcare” (*European Commission official*).

With the virus's disease profile evolving faster than prospective preventatives or therapies, Member States (e.g., European Council, 2020), the WHO (e.g. World Health Organisation, 2020), the OECD (e.g., OECD, 2020), EU institutions (e.g., European Parliament, 2020) and interest associations (EU4Health, 2020) all publicised the detrimental effects of resource scarcity on population health to the EU arena. Notably, the EP highlighted how the pandemic has “exposed the difference in capacity between the Member States' healthcare systems” to the extent that “some Member States may become reliant on their neighbouring countries having a sufficiently resilient system” (European Parliament, 2020).

⁷ The principle of subsidiarity is laid out in Article 5(3) of the Treaty of the European Union and states that the EU does not take action (except in the areas that fall within its exclusive jurisdiction), unless it is more effective than action taken at the national, regional or local level (European Union, 2012). As health policy is considered a sensitive area, shaped by national needs and priorities, it is predominantly exercised at the Member State rather than the supranational level.

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For the EU pharmaceutical policy sector, this signified a return to centre stage for the set of problems that had underpinned the initial rise of the revision of the General Pharmaceutical Legislation and the new HTA framework on the policy agenda during the latter half of the 2010s. Both agendas were motivated by concerns over the pricing and availability of medicines across the EU, as well as inconsistencies in access and affordability between Member States, as articulated by the Council of Health Ministers and key interest groups—most notably patient associations (Karokis-Mavrikos, 2025b; Council of the European Union, 2016; Council of the European Union, 2014). Following the outbreak of COVID-19, these challenges returned to the forefront this time with heightened and less ambiguous severity.

EU Competencies in Medical Countermeasures and Public Health

Second, the pandemic surfaced issues related to scope of the EU's competencies in health and pharmaceutical policy.

One side of this problematisation concerned the effectiveness of routine policymaking under crisis conditions. Drawing on the competencies of the European Medicines Agency (EMA)—the EU's dedicated authority for approving medicines for circulation in the EU single market—the EU was able, from the early stages of the pandemic, to invest in the rapid development and timely dissemination of vaccines. As highlighted by a veteran representative of the EMA, by 2020 “seven scientific committees” were “operating within the Agency, promoting the quick and comprehensive evaluation of a wide range of medicinal products, including vaccines.” Moreover, previous pilot schemes for accelerated approval, such as PRIME (Mullard, 2017), “provided the technical know-how to evaluators and developers, helping to reduce transactional losses in time-pressuring circumstances” (pharmaceutical industry representative). As a result, the organisation possessed the resources, personnel, and mandate required to deliver continuous scientific advice to developers and to conduct rolling reviews for dedicated COVID-19 medical countermeasures, while existing institutional infrastructure enabled the joint procurement of COVID-19 vaccines.

However, in contrast to vaccines, medical countermeasures that were not developed specifically for the prevention or treatment of COVID-19 lacked comparable EU-level monitoring and distribution mechanisms. From the early stages of the crisis, “shortages in anaesthetics, antibiotics, muscle relaxants, and off-label medicines were reported in most Member States” (*EMA official*), with information published repeatedly across fragmented national-level platforms (Beck & Buckley, 2022). By July 2020, the European Parliament had highlighted that “the COVID-19 pandemic [...] has aggravated [...] the longstanding problem of shortages of medicines within the EU, [...] which has worsened exponentially in recent years, entailing considerable risks for the health and care of patients.” Pharmaceutical manufacturers, who were called upon to mitigate shortages on an emergency basis while simultaneously facing supply-chain disruptions, communicated that effective supply management without “an EU prevention and mitigation system, based on a standard definition of a shortage and an interoperable EU-wide IT monitoring and notification platform,” is not feasible (*EFPIA, 2022*).

Moreover, even greater deficiencies in capacity and infrastructure emerged with regard to prevention and preparedness. Unlike medical countermeasures, prevention and preparedness extend beyond the management of pharmaceutical commodities and therefore fall outside the strict confines of

pharmaceutical policy, instead tapping into the domain of public health, where the EU holds limited executive powers (Article 168 TFEU; European Union, 2008). As a result, at the time of the COVID-19 outbreak, the EU lacked both a dedicated instrument for pandemic preparedness and an institutionalised process for declaring a public health emergency. At the same time, as the pandemic's likely long-term effects became rapidly apparent, the EU was also missing centralised mechanisms to macro-manage the unfolding public health crisis. Similar to the case of health system inequalities, these issues had previously risen on the policy agenda during the 1990s, culminating in unsuccessful attempts by the European Commission to extend single market competences for medicines to pricing and reimbursement (Kanavos & Mossialos, 1999). This time, however, the EU's limited public health competences became closely intertwined with the problematisation of health system inequalities, mutually reinforcing momentum for agenda attention and mobilisation.

In sum, following a systemic focusing event, the EU pharmaceutical policy sector's problem stream saw the parallel emergence of problems concerning both the threats posed by the COVID-19 outbreak and the challenges of pandemic management at the EU-level. Issues rising to the EU arena primarily focused on the fragility of national health systems, inequalities in patient outcomes, and the capacity and scope of EU pharmaceutical policy instruments. Crucially, emerging problems showed high interconnectedness, both with one another and with the sector's recent pre-crisis experience. Therefore, the challenges of normalcy and crisis became conflated upon the opening of the problem-driven policy window.

The Policy Stream

Having outlined the interconnected challenges facing the EU pharmaceutical sector in the wake of the COVID-19 outbreak, the analysis shifts to the policy stream, evaluating the relative prioritisation and preferences of the sector's policy stakeholders regarding the concurrent policy reforms that took place in the outbreak's aftermath.

The EU Pharmaceutical Sector's Policy Network(s)

First, drawing on the Q-Methodology inputs, the outlooks of the sector's stakeholders aggregated across reforms. Specifically, three dominant viewpoints are identified within the EU pharmaceutical sector based on the loading of participants to their dominant factors (Table 2).

Table 2: Participant Factor Loadings			
Participant	Factor 1	Factor 2	Factor 3
Commission 1	0.81	0.14	0.22
Commission 2	0.79	0.20	0.30
Commission 3	0.87	0.12	-0.10
Patients' Association 1	0.08	0.85	0.10
Patients' Association 2	0.26	0.89	0.04

Patients' Association 3	-0.01	0.90	-0.15
EUnetHTA	0.85	-0.06	0.14
Pharmaceutical Industry 1	0.23	-0.14	0.86
Pharmaceutical Industry 2	0.09	0.06	0.88
Pharmaceutical Industry 3	-0.01	-0.09	0.91
EP 1	0.50	0.62	-0.02
EP 2	0.57	0.40	-0.20
Council 1	0.67	0.20	-0.25
Council 2	0.38	-0.22	-0.42
EMA	0.74	0.19	0.42

**Darker shading indicates dominant loading and factor assignment*

Table 2: Participant Factor Loadings

Observing the composition of factors and calculating mean factor loadings by institutional affiliation (Table 3) sketches a highly informative categorical breakdown. First, an “institutional viewpoint” is shared most prominently by the Commission (mean loading = 0.82), EMA (0.74), and EUnetHTA (0.85), and secondarily by the European Parliament (0.54) and the Council (0.53). Second, a “patients’ viewpoint” is shared primarily by representatives of patient associations (0.88) and, to a lesser extent, by the European Parliament (0.51). Finally, a “pharmaceutical industry” viewpoint is most strongly associated with industry representatives (0.88) and, more moderately, with the EMA (0.44).

In the immediate aftermath of the COVID-19 pandemic, the two sides of the EU pharmaceutical policy sector’s interest ecosystem appear to articulate polarised and highly differentiated policy outlooks, as further evidenced by several negative mean loadings of participants on Factors 2 and 3 (Table 3). At the same time, the sector’s key policy instruments and institutions display a higher degree of alignment in their policy viewpoints, although this convergence is more pronounced among strictly supranational bodies, such as the European Commission and the EMA.

Table 3: The Three Viewpoints of the EU Pharmaceutical Policy Sector			
Actor/Institution	Mean Loading		
	The Institutional Viewpoint (Factor 1)	The Patients Viewpoint (Factor 2)	The Pharmaceutical Industry Viewpoint (Factor 3)
Commission	0.82	0.15	0.14
EUnetHTA	0.85	-0.06	0.14
EMA	0.74	0.19	0.42
EP	0.54	0.51	-0.11

Council	0.53	-0.01	-0.34
Patients' Associations	0.11	0.88	0
Pharmaceutical Industry	0.1	-0.06	0.88

Table 3: The Three Viewpoints of the EU Pharmaceutical Policy Sector

Second, policy agendas predating COVID-19 rank higher in the sector's order of priorities. In Q-methodology, beyond expressing general agreement or disagreement with statements through positive or negative rankings, participants also indicate the relative importance they assign to specific options through their placement on the Q-grid. While statements placed in the “-1,” “0,” and “1” slots fall within a broader zone of indifference, those located in the more constrained “+3” and “-3” slots signal high salience. Accordingly, by computing the mean absolute value of statement rankings within each thematic category, this study derives a metric for assessing the relative importance of policy agendas between different sets of stakeholders.

Across all three factors, statements related to the revision of the General Pharmaceutical Legislation receive the highest mean absolute ranking (1.77), followed by statements concerning the new EU HTA framework (1.67) and those addressing post-COVID-19 resilience (1.00) (Table 4). While the pandemic undoubtedly monopolised the policy community's attention from 2020 onwards, as highlighted in the problem stream, stakeholders continued to regard antecedent policy agendas as the most consequential for the sector's future policy trajectory at the time of administering the exercise (2023).

Third, each policy agenda is prioritised significantly more highly by a different cluster of stakeholders (Table 4). Statements related to the General Pharmaceutical Legislation receive the highest mean absolute ranking from the “pharmaceutical industry” viewpoint (2.20), followed by the “patients” (1.70) and “institutional” (1.40) viewpoints. By contrast, the HTA agenda is prioritised most strongly by the “patients” viewpoint (mean absolute ranking of 2.00), followed by the “institutional” (1.67) and “pharmaceutical industry” (1.33) viewpoints. Finally, statements related to post-COVID-19 resilience are ranked highest, in terms of mean absolute value, by the “institutional” viewpoint (1.57), followed by both the “pharmaceutical industry” and “patients” viewpoints (0.71 each).

Finally, combining the relative prioritisation of policy agendas with the average absolute difference in statement rankings across each provides a measure of relative policy network integration. The concept of fluid participation, which is central to the MSF, captures the continuous choices actors face regarding which policy developments to invest their limited resources in. Highly integrated policy networks exhibit lower variance in actor participation, reflecting stronger barriers to entry, more institutionalised modes of stakeholder interaction, and more crystallised policy preferences among participants (Herweg et al., 2018; Zahariadis, 2003). As a result, policy agendas in highly integrated networks are expected to be more strongly prioritised by actors—compared to those in weakly integrated networks—who, in turn, are likely to support or oppose policy alternatives with similarly high levels of intensity.

In the case of EU pharmaceutical policy, developments related to market authorisation and pharmaceutical incentives receive the highest mean absolute ranking across the three factors (1.77) and display the second-lowest variation in ranking intensity between stakeholders (0.53), indicating a highly integrated policy network (Table 4). The HTA agenda exhibits a similar, albeit less pronounced, pattern, suggesting a network moving towards higher levels of integration. While stakeholders rank HTA-related statements with the lowest variation in intensity (0.44), these are expressed at lower overall levels of prioritisation (mean absolute value of 1.67) compared to the General Pharmaceutical Legislation. By contrast, the policy network on emergency preparedness and response appears the least integrated. It is characterised by the lowest mean absolute ranking (1.00) and the highest variation in ranking intensity between stakeholder clusters (0.57). Engagement in this area appears to be driven almost exclusively by institutional actors, most prominently the European Commission, with the network’s relative importance yet to rival that of policy agendas predating the pandemic and patterns of participation still in the process of consolidation.

Table 4: Relative Importance of Policy Agendas for Stakeholder Viewpoints					
Policy Agenda	Mean Absolute Ranking: The Institutional Viewpoint	Mean Absolute Ranking: The Patients Viewpoint	Mean Absolute Ranking: The Pharmaceutical Industry Viewpoint	Mean Absolute Ranking: Overall	Mean Difference in Average Absolute Ranking
General Pharmaceutical Legislation	1.40	1.70	2.20	1.77	0.53
HTA	1.67	2.00	1.33	1.67	0.44
Covid-19	1.57	0.71	0.71	1	0.57

Table 4: Relative Importance of Policy Agendas for Stakeholder Viewpoints

Policy Preferences and Priorities Across Reform Agendas

Beyond assessing the relative prioritisation of reforms by different stakeholder clusters and the degree of policy network integration across concurrent agendas, the incorporation of Q-Methodology into the EU-MSF policy stream adds a further analytical layer. It enables the systematic assessment of actors’ policy preferences across reform alternatives and the identification of areas of consensus and divergence. In doing so, Q-Methodology provides a measure of value acceptability—one of the two key criteria for the success of policy alternatives in MSF scholarship—and helps identify which stakeholder clusters are more successful in shaping policy outputs, especially under conditions of dissensus. At the same time, by tracing patterns in policy preferences and priorities across reforms, it enables an assessment of shifts in the sector’s overarching value orientation during a period of intense policy change.

The Revision of the General Pharmaceutical Legislation

The revision of the General Pharmaceutical Legislation was concluded in December 2025, reconfiguring the EU framework for the authorisation of innovative medicines and shifting towards a system of more restricted and highly conditional incentives for developers, more closely linked to addressing unmet medical needs, medicine shortages, and antimicrobial resistance (Council of the European Union, 2025). The reform marked a fundamental change in direction for the policy framework, which for more than two decades had prioritised the maximisation of incentives to offset the high costs and uncertainty of pharmaceutical innovation (Regulation (EC) No 726/2004; Directive 2001/83/EC). The administration of the Q-Methodology exercise between March and June 2023 coincided with the publication of the European Commission's proposal initiating the legislative process (European Commission, 2023a; European Commission, 2023b), which envisaged an even more strongly conditional incentive structure than the one ultimately agreed upon by the European Parliament and the Council in 2025. As a result, the Q-Methodology inputs shed unique light on the preference configurations underpinning the observed policy shift, as well as on the sources of friction that emerged during agenda-setting and policy deliberation.

For both the “patients” and “institutional” viewpoints, a fundamental reconfiguration of pharmaceutical incentives emerged as a strongly favoured approach to steer R&D towards current and future health challenges—such as orphan diseases and antimicrobial resistance—and to reduce the risk of future health crises (factor arrays of “2” and “1”, respectively; Statement 1, Table 5). A similarly favourable, albeit more moderate, stance was expressed by these stakeholder clusters with regard to curbing intellectual property protections to facilitate the earlier market entry of generics (factor arrays of “0” for institutional actors and “1” for patients; Statement 2, Table 5). These positions stood in clear contrast to the pharmaceutical industry's viewpoint, which emphasised that reducing baseline market exclusivity and increasing conditionality risked encouraging indicator gaming rather than delivering greater availability of critically needed medicinal products (factor arrays of “-2” for both patients and institutional actors, and “1” for industry; Statement 3, Table 5).

For the pharmaceutical industry, which signalled disagreement with both Statements 1 and 2 (factor arrays of “-1” and “-3”, respectively; Table 5), the policy approach expressed by the “institutional” and “patients” viewpoints—and reflected in the Commission's 2023 proposal—contradicted the lessons drawn from the early stages of the pandemic response. According to the industry, the accelerated development of vaccines and the adaptability exhibited by pharmaceutical supply chains under adverse circumstances strongly underscored how *“a globally competitive and resilient pharmaceutical innovation industry should be the EU's leading vehicle for responding to patients' needs”* (factor array score of “3”, compared to “-2” for the “patients” and “0” for the “institutional” viewpoint; Statement 4, Table 5). While the industry did not oppose redefining innovation to focus on added health value and unmet medical need (factor array score of “0”, compared to “3” for patients and “2” for institutional actors; Statement 5, Table 5), it objected to the policy options supported by the “institutional” and “patients” viewpoints on grounds of proportionality.

Ultimately, while the pharmaceutical industry expressed strong support for tackling high medicines' prices predominantly through pricing and reimbursement reforms at the Member State level (factor array score of "3"), the rest of the sector's ecosystem appeared heavily invested in EU-level solutions, in the form of adjusting pharmaceutical innovation incentives (factor array scores of "-2" and "-1" for the "institutional" and "patients" viewpoints, respectively, Statement 6, Table 5). The observed reconfiguration of value acceptability aligned closely with the outlook of patients' associations, pointing to their rise as a formidable interest stakeholder within the policy network, while also highlighting an important shift among institutional actors, who for the first time at this scale supported sacrificing single-market optimisation in pursuit of improved health outcomes.

Table 5: Policy Positions on the Revision of the General Pharmaceutical Legislation					
Statement Number	Description	Factor Array: The Institutional Viewpoint	Factor Array: The Patients Viewpoint	Factor Array: The Pharmaceutical Industry Viewpoint	Distinguishing/ Consensus
1	Decreasing the baseline regulatory protection period and expanding conditional exclusivity incentives can drive more focused innovation, addressing challenges like orphan diseases and AMR	2	1	-1	Distinguishes f3 only
2	The best approach to contain high medicines' prices in the EU is to restrict pharmaceutical innovation incentives and promote the quicker entry of generics to the market	0	1	-3	Distinguishes f3 only
3	Lowering baseline market exclusivity and emphasising conditionality threatens to promote indicator-gaming, orienting pharmaceutical research exclusively towards regulatory-favourable products	-2	-2	1	Distinguishes f3 only
4	A globally competitive and resilient pharmaceutical innovation industry should be the EU's leading vehicle for responding to patients' needs	0	-2	3	Distinguishes All
5	There is a need to redefine "innovation" in the field of pharmaceuticals, focusing on added health value and addressing unmet medical need	2	3	0	Distinguishes All
6	The best approach to contain high medicines' prices in the EU is to promote regulatory and budgeting reforms at the member state level, to improve the pricing and reimbursement process	-2	-1	3	Distinguishes All

Table 5: Policy Positions on the Revision of the General Pharmaceutical Legislation

The EU HTA Framework

The EU HTA framework was adopted in 2022 and entered into effect in January 2025, following a three-year preparatory period. Regulation (EU) 2021/2282 introduced, for the first time, a formal and permanent framework for EU-level collaboration in the assessment of the added value of new health technologies, including provisions for the conduct of Joint Clinical Assessments (JCAs) for all innovative medicines at the EU level. Previously, health technology assessments were conducted almost exclusively at the Member State level, contributing to discrepancies in pricing and reimbursement outcomes across the Union.

The reform marked the conclusion of a legislative process that began in 2018 with a highly ambitious Commission proposal (European Commission, 2018), before interinstitutional negotiations scaled back the obligations for joint assessments and introduced a phased implementation timeline. At the time the Q-Methodology exercise was administered, stakeholders were deliberating both the consolidation of the framework's launch and the scope of potential future steps.

In the case of the EU HTA framework, Q-Methodology revealed a high degree of consensus. All three stakeholder viewpoints expressed a strong preference for expanding the centralised HTA procedure (factor arrays of “3” for the “institutional” viewpoint and “2” for both “patients” and the “pharmaceutical industry”; Statement 1, Table 6). At the same time, they expressed disagreement with granting discretion over the uptake of joint outputs and generally opposed exclusive executive oversight of the new system by Member States (factor arrays of “-1” for the “institutional” viewpoint, “-3” for patients, and “-2” for the “pharmaceutical industry”; Statements 2 and 3, Table 6)—amendments that were introduced by the Council into the final version of the Regulation. As expected, the “institutional” viewpoint expressed comparatively weaker support for mandatory uptake and for the sharing of executive responsibilities, driven by the loading of Council representatives onto the factor, albeit with a lower weighted contribution relative to the Commission, the European Parliament, the EMA, and EUnetHTA.

Here, Q-Methodology uniquely illuminated the relative drivers of value acceptability surrounding the provisions of the new EU HTA framework. Improvements in domestic health outcomes were most strongly emphasised by the “institutional” viewpoint, which expressed a firm belief that the new EU HTA regime would improve pricing and reimbursement decisions within national health systems (factor array score of “3”, compared to “-1” for the “patients” and “1” for the “pharmaceutical industry” viewpoints; Statement 4, Table 6). For the “patients” viewpoint, greater emphasis was placed on improvements in quality standards (factor array score of “2”, compared to “1” for both the “institutional” and “pharmaceutical industry” viewpoints; Statement 5, Table 6), as well as on enhanced inclusiveness and transparency (factor array score of “3”, compared to “-3” for the “institutional” and “1” for the “pharmaceutical industry” viewpoints; Statement 6, Table 6). For the “pharmaceutical industry” viewpoint, transactional and regulatory efficiency gains remained of paramount importance, as participants viewed the new JCA framework as overly burdensome (factor array score of “2”, compared to “-2” for the “institutional” and “-3” for the “patients” viewpoints; Statement 7, Table 6).

Table 6: Policy Positions on the new EU HTA Framework					
Statement Number	Description	Factor Array: The Institutional Viewpoint	Factor Array: The Patients Viewpoint	Factor Array: The Pharmaceutical Industry Viewpoint	Distinguishing/ Consensus
1	The future of EU HTA should rely on promoting robust and transparent standards for the benefit of EU patients. Hence, an expanded centralised procedure with mandatory uptake is necessary	3	2	2	Consensus
2	The future of EU HTA should rely on promoting robust and transparent standards, which respond to the demands of EU citizens. Hence, member state discretion over the uptake of joint outputs is necessary	-1	-3	-2	Distinguishes f1 only
3	Member States must have exclusive executive responsibilities over the EU HTA framework, including the development of methodologies, the selection of technologies, the execution of JCAs and JSCs, and horizon scanning.	-1	-3	-2	Distinguishes f2 only
4	The new EU HTA framework will lead to more favourable pricing and reimbursement decisions for patients and health systems	3	-1	1	Distinguishes f1 only
5	Harmonisation in EU HTA needs to primarily address issues of resources and expertise to prevent a "race to the bottom" in terms of evaluation standards	1	2	1	Distinguishes f2 only
6	The new EU HTA framework is insufficiently inclusive, excluding patients from the locus of decision-making	-3	3	-1	Distinguishes All
7	Expanding Joint Clinical Assessments aims at reducing transactional costs, but the currently proposed framework will be overly burdensome for manufacturers and regulators	-2	-3	2	Distinguishes f3 only

Table 6: Policy Positions on the new EU HTA Framework

Emergency Preparedness and Response

The third category of reforms advanced as part of the European Health Union concerns initiatives related to public health emergency preparedness and response. These included, most prominently, extending the mandate of the EMA to monitor medicine shortages, establishing a dedicated EU Health Emergency Preparedness and Response Authority (HERA) with strategic responsibilities, and adopting a new Regulation on Serious Cross-Border Health Threats. Importantly, unlike the revision of the General Pharmaceutical Legislation and the new EU HTA framework, these initiatives were introduced and adopted as a direct response to the COVID-19 outbreak, often through expedited institutional processes. For example, HERA was initially established as an internal agency of the European Commission before receiving formal recognition and Directorate-General status in 2022 with the adoption of the Serious Cross-Border Health Threats Regulation.

Here, Q-Methodology highlighted that stakeholders in the sector—particularly non-institutional actors—appeared sceptical about whether the impact of these reforms would extend beyond the confines of the COVID-19 pandemic. For example, while the “institutional” viewpoint categorically rejected recurring criticism regarding the one-dimensional focus of HERA on antiviral stockpiling (factor array score of “3”; Statement 1, Table 7), both the “patients” and “pharmaceutical industry” viewpoints expressed neither agreement nor disagreement with this claim (factor array scores of “0”). A similar pattern, albeit with greater convergence, was observed regarding the transferability of joint vaccine procurement mechanisms to non-crisis contexts (factor array scores of “-1” for the “institutional”, “0” for the “patients”, and “-2” for the “pharmaceutical industry” viewpoints; Statement 2, Table 7).

Ultimately, while all three viewpoints rejected the notion that the COVID-19 response consisted merely of symbolic interventions (factor array scores of “-3” for the “institutional”, “-2” for the “patients”, and “-1” for the “pharmaceutical industry” viewpoints; Statement 3, Table 7), none expressed strong confidence that the EU had developed a resilient framework for public health security in the pandemic’s aftermath (factor array scores of “1” for the “institutional” and “-1” for both the “patients” and “pharmaceutical industry” viewpoints; Statement 4, Table 7).

Table 7: Policy Positions on the EU’s framework for Public Health Emergency Preparedness and Resilience

Statement Number	Description	Factor Array: The Institutional Viewpoint	Factor Array: The Patients Viewpoint	Factor Array: The Pharmaceutical Industry Viewpoint	Distinguishing/ Consensus
1	Despite an ambitious scope, the functioning of HERA appears restricted to the realm of pharmaceutical stockpiling	-3	0	0	Distinguishes f1 only
2	The joint procurement of vaccines should be the blueprint for EU pharmaceutical production and supply challenges in times of normalcy and crisis	-1	0	-2	Distinguishes f3 only

3	EU-level policies during the Covid-19 response consisted of limited-scope, symbolic interventions	-3	-2	-1	Distinguishes f1 only
4	The European Health Union has given rise to a framework for sustained public health security	1	-1	-1	Distinguishes f1 only

Table 7: Policy Positions on the EU's framework for Public Health Emergency Preparedness and Resilience

Sectoral Shifts in Value Orientation

Observing patterns across policy agendas, the latest reformative wave in the EU pharmaceutical policy sector—consolidated under the European Health Union—completed a shift in the sector's value orientation away from viewing policy primarily as a response to Single Market challenges and towards approaching it as a response to health-related needs. Across all three stakeholder viewpoints, there was consensus agreement with the statement "Recent reforms in EU pharmaceutical policy have been motivated by changing health needs and disease profiles", alongside consensus indifference (factor array score of "0") towards the statement "Recent reforms in EU pharmaceutical policy have been motivated by suboptimalities in the functioning of the internal market." Notably, the "pharmaceutical industry" viewpoint expressed the strongest agreement with the former statement, with a factor array score of "2", compared to "1" for both the "patients" and "institutional" viewpoints. That the strongest agreement came from actors traditionally most invested in Single Market optimisation underscores a clear recognition of the shifting policy reality.

However, it should be noted that this does not imply that the sector has operated under consensus—far from it. For example, in the case of the revision of the General Pharmaceutical Legislation, despite acknowledgement of the need to prioritise unmet medical needs and address future vulnerabilities in access, the pharmaceutical industry firmly opposed the transformation of pharmaceutical incentives into a primary instrument for shaping Member State health system outcomes. Similarly, initiatives related to health emergency preparedness and response—although most directly linked to health-related objectives—continued to rank lower in stakeholders' priorities and were met with greater scepticism than the more established, commodity-oriented policy agendas surrounding HTA and pharmaceutical incentives.

Nevertheless, despite the friction in preferences and policy positions, the European Health Union era has marked the most transformative period in the history of the EU pharmaceutical policy sector in both volume and scope, as these concurrent reformative agendas have emerged as responses to the challenges surfaced by the COVID-19 pandemic, while being supported by consistent political momentum.

The Politics Stream: The European Health Union Narrative

The EU-MSF's politics stream places particular emphasis on narratives, as the rigidity and long-term orientation of EU decision-making processes mean that political determination depends less on legislative turnover and more on shifts in political visions across EU institutions. When evaluating sectoral-level shifts in policy outlook in the aftermath of a public health crisis, it is therefore important to draw on the relevant scholarship on crisis narratives and to distinguish between the “instrumental” function of narratives—aimed at encouraging public support for crisis-response choices—and the “political” function of narratives, which seeks to foster public trust and confidence in the functioning of institutions, systems, and processes in the post-crisis period (Boin et al., 2021).

In the case of the emergency preparedness and response initiatives instituted in the immediate aftermath of the COVID-19 outbreak, EU action—most notably led by the European Commission—reflected the shared “instrumental” narrative, namely that policy initiatives at all levels should prioritise the protection of EU citizens from the unfolding public health threats. Despite past contestation over the scope of EU jurisdiction in public health, convergence in this instance was clearly reflected in stakeholder rankings of the statement “the COVID-19 pandemic has highlighted the need for more substantive EU involvement in public health matters”, which received a factor array score of “2” from the “institutional” viewpoint. During the early stages of the COVID-19 crisis, public health protection took precedence over all other considerations. In doing so, it simultaneously aligned with the Commission's narrative of a “functional” public through enhanced coordination, the Council's narrative of a “ruling” public through improved resource mobilisation, and the European Parliament's narrative of a “popular” public by foregrounding citizen protection over high-level political contestation.

However, transitioning from the “instrumental” to the longer-term “political” function of narratives pits the politics of crisis against the politics of normalcy. Specifically, the extent to which the crisis-driven convergence in institutional narratives can persist during post-crisis policymaking largely determines the extent to which it can underpin longevous change. In the case of the EU pharmaceutical policy sector, amidst the mass mobilisation around health inequalities and the Europeanisation of domestic health challenges induced by the pandemic, the frames of health security and resilience emerged as unifying elements connecting the pre- and post-pandemic trajectory of the stream. This is strongly reflected in the way European Health Union initiatives have been presented by political officials, particularly within the European Commission, where explicit references to public health are notably absent, while terms such as “empowerment”, “equality”, “timeliness”, “affordability”, and “reliability” recur prominently.

Ultimately, the often ambiguously defined European Health Union embodies the “political function” of narratives, serving as an overarching frame to underpin post-crisis policymaking and, in doing so, shaping the policy direction of the EU pharmaceutical policy sector across reforms. More specifically, it enabled the European Commission to extend the window of opportunity opened by the COVID-19 outbreak beyond the pandemic's conclusion.

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The set of policy initiatives aimed at strengthening the EU's crisis preparedness and management infrastructure—particularly in relation to medical countermeasures—emerged during a problem-stream window triggered by a systemic focusing event. However, reliance on a crisis-driven problem window to advance antecedent policy agendas is constrained by issues of prioritisation and timing. Crisis windows are inherently fleeting: crisis-containment policies supersede all other priorities and, paradoxically, the more effective the response, the more quickly the window closes. This dynamic is reflected in the relatively low mean absolute ranking assigned by Q-Methodology participants to initiatives directly connected to crisis response, given that the exercise was conducted in 2023.

To capitalise on crisis momentum not only in the short term but also over the medium and long term, the Commission therefore relied on the European Health Union narrative to transform a problem-driven window of opportunity into a political one. Since 2020, actors and institutions in the EU pharmaceutical policy sector have consistently linked ongoing and emerging initiatives to the European Health Union project, allowing momentum to diffuse from emergency preparedness and response towards health system resilience and health-outcomes-oriented regulatory reforms. Against this backdrop, it is unsurprising that Q-Methodology participants moderately rejected the statement “The COVID-19 disruption reconfigured the ongoing policy agendas of the EU pharmaceutical policy sector” (factor array scores of “-1” for both the “institutional” and “pharmaceutical industry” viewpoints, and “0” for “patients”).

Overall, amid a convergence of narratives on health security and resilience, the sector has leveraged the momentum of the COVID-19 crisis, even beyond the outbreak's containment, opening a window in the political stream to advance pre-existing reformative processes, enhance institutional interconnectedness, and subtly extend the EU's public health mandate.

Discussion – Conclusion

How do policy stakeholder preferences across concurrent policy agendas shape policy outputs and the overarching value orientation of a policy sector? And how does crisis affect this process?

Focusing on the emergence of the European Health Union, this study contributes to answering these questions by introducing analytical, methodological, and empirical advancements to policy process research, EU studies, crisis politics, and health policy scholarship.

The analysis applied the EU-MSF—a modified iteration of the MSF tailored to the EU political system—through a mixed-methods research design combining document analysis, elite interviews, and Q-Methodology. In the problem stream, the analysis concluded that the COVID-19 pandemic tested the sustainability of Member States' health systems, exposed inequalities in health outcomes across EU patients, and scrutinised the institutional capacity of the EU pharmaceutical policy sector across both pharmaceutical and public health functions. Crucially, the nature of the crisis as a public health emergency allowed long-standing problems facing the sector to surface simultaneously, underscoring their interconnectedness while constraining framing contests.

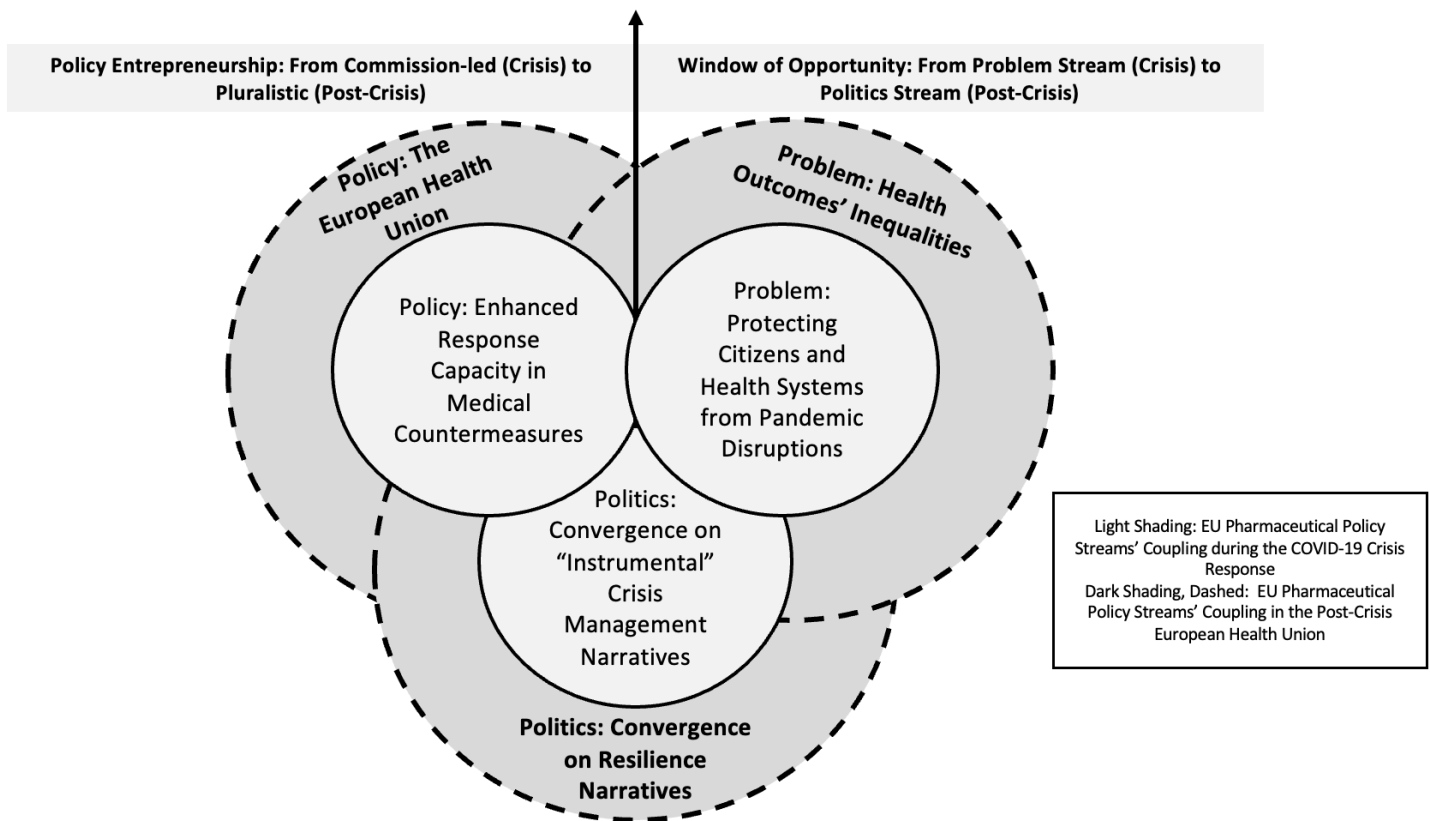
In the face of such a wide-reaching, problem-driven window of opportunity, policy actors found favourable conditions to advance both new and ongoing policy agendas. As the analysis demonstrated, however, even as these reform processes unfolded concurrently within the sector, stakeholders exhibited markedly different patterns of prioritisation across them, generally attributing greater significance to agendas that had been initiated prior to the COVID-19 outbreak.

Ultimately, the analysis highlighted that, across reforms, EU pharmaceutical policy stakeholders have coalesced around three overarching policy viewpoints: one most strongly articulated by supranational institutions and policy instruments, one most prominently expressed by patients' associations, and one most clearly associated with the pharmaceutical innovation industry. This configuration has signaled a newly emergent pluralism within the sector, as patients' associations have consolidated their position as a rival voice to the traditionally dominant pharmaceutical innovation industry. Crucially, convergence between the institutional and patients' viewpoints has been both more frequent and more consequential than convergence between the pharmaceutical industry and either of the other two perspectives.

At the same time, the sector has experienced a clear shift in its prevailing value orientation, towards the pursuit of health-oriented rather than single-market-focused policy outcomes. On the one hand, this shift has been driven by changes in value acceptability, reinforced by the widespread surfacing of health and public health challenges under pandemic conditions, as well as by the unique position of the EU pharmaceutical policy sector as the Union's primary vehicle for advancing public health objectives. On the other hand, it has been reinforced by narrative convergence around health security and resilience. In sum, the European Health Union can be understood as an extension of pandemic-generated momentum into the post-pandemic period, driven by EU institutions—most notably the European Commission—strategically mobilising the political function of crisis narratives. In this way, a concentric coupling process can be argued to have been pursued, carrying the momentum generated by emergency preparedness

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initiatives introduced during the immediate crisis response into major transformations in pharmaceutical incentives and health technology assessment that had been decades in the making.



Beyond its empirical findings, the study makes a series of theoretical and methodological contributions that can inform future research. First, it demonstrates the analytical value of the EU-MSF as a framework for explaining policy change in the contemporary EU political system. By capturing the dynamic interaction of policy drivers—crisis, problem surfacing, preference constellations, narratives, and momentum—it improves upon more unidimensional approaches in European integration scholarship, as well as policy process frameworks that lack adaptations tailored to the EU context.

Second, the study highlights the capacity of the EU-MSF—and, by extension, MSF research—to be applied not only at the level of individual policy programmes, but also at the sectoral level. This is essential for understanding periods of system-wide reform, in which shifts in policy preferences and priorities might extend beyond single initiatives and spill over across concurrent reform processes. Third, it demonstrates how Q-Methodology can be leveraged to support the systematic measurement of key MSF policy stream variables, including policy network integration and value acceptability. The limited extent of systematic empirical testing within MSF scholarship (Weible & Schlager, 2016) has often been attributed to the relatively small number of quantitative or mixed-methods research designs (Jones et al., 2016), a pattern

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observed across much of the policy change literature more broadly (e.g., Pierce et al., 2020). While quantitative approaches are by no means a prerequisite for rigorous policy process research—given the meso-level nature of analysis and persistent data constraints—the value of quantifiable measures for strengthening the robustness of MSF applications has long been recognised (Travis & Zahariadis, 2002). This study contributes an approach that leverages this value while retaining the fieldwork-based elements that remain central to policy process research.

Fourth, the metrics developed for relative issue prioritisation and policy network integration, as well as the assessments of convergence between stakeholder viewpoints and policy outputs, constitute broader methodological innovations within Q-Methodology and public policy scholarship. These contributions can inform future research on policy preference aggregation and relative stakeholder influence, including potential methodological extensions such as the incorporation of quantitative text analysis to capture relative influence over policy outputs even more granularly.

Finally, the use of narratives as a proxy for political momentum offers a transferable analytical strategy for contexts in which administrative or legislative turnover is a less meaningful indicator of shifting political determination. At the same time, the finding that stakeholders can strategically leverage the political function of narratives to extend crisis momentum beyond acute shocks also opens promising avenues for further research in the literatures on crisis politics and policy entrepreneurship.

References

- Ackrill, R., Kay, A., & Zahariadis, N. (2013). Ambiguity, multiple streams, and EU policy. *Journal of European Public Policy*, 20(6), 871–887. <https://doi.org/10.1080/13501763.2013.781824>
- Atkinson, E. (2004). What makes a good primary school teacher? Expert classroom strategies using Q methodology. *British Educational Research Journal*, 30(1), 157–171. <https://doi.org/10.4324/9781315648736>
- Bache, I. (2012). Measuring quality of life for public policy: An idea whose time has come? Agenda-setting dynamics in the European Union. *Journal of European Public Policy*, 20(1), 21–38. <https://doi.org/10.1080/13501763.2012.699658>
- Beck, M., & Buckley, J. (2022). Managing pharmaceutical shortages during the COVID pandemic: An exploratory analysis of European collective and national government responses. *Journal of Medical Access*, 6, 1–12. <https://doi.org/10.1177/27550834221123425>
- Benson, D., & Russell, D. (2015). Patterns of EU energy policy outputs: Incrementalism or punctuated equilibrium? *West European Politics*, 38(1), 185–205. <https://doi.org/10.1080/01402382.2014.936707>
- Boin, A., McConnell, A., & 't Hart, P. (2021). Crafting crisis narratives. In *Governing the pandemic* (pp. 65–85). Palgrave Pivot. https://doi.org/10.1007/978-3-030-72680-5_4
- Borrás, S., & Radaelli, C. M. (2011). The politics of governance architectures: Creation, change and effects of the EU Lisbon Strategy. *Journal of European Public Policy*, 18(4), 463–484. <https://doi.org/10.1080/13501763.2011.560069>
- Brooks, E. (2018). Using the Advocacy Coalition Framework to understand EU pharmaceutical policy. *European Journal of Public Health*, 28(Suppl. 3), 11–14. <https://doi.org/10.1093/eurpub/cky153>
- Brown, S. R., Durning, D. W., & Selden, S. C. (2008). Q methodology. In K. Yang & G. J. Miller (Eds.), *Handbook of research methods in public administration* (2nd ed., pp. 721–763). Routledge.
- Burgess, M. (2000). *Federalism and the European Union: The building of Europe, 1950–2000*. Routledge.
- Cairney, P., & Jones, M. D. (2016). Kingdon's multiple streams approach: What is the empirical impact of this universal theory? *Policy Studies Journal*, 44(1), 37–58. <https://doi.org/10.1111/psj.12111>
- Citi, M. (2013). EU budgetary dynamics: Incremental or punctuated equilibrium? *Journal of European Public Policy*, 20(8), 1157–1173. <https://doi.org/10.1080/13501763.2013.781806>
- Cohen, M., March, J., & Olsen, J. (1972). A garbage can model of organizational choice. *Administrative Science Quarterly*, 17(1), 1–25. <https://doi.org/10.2307/2392088>
- Council of the European Union. (2014). Council conclusions on innovation for the benefit of patients (2014/C 438/06). *Official Journal of the European Union*.
- Council of the European Union. (2016). Council conclusions on strengthening the balance in the pharmaceutical systems in the European Union and its Member States (2016/C 269/31). *Official Journal of the European Union*.

This is a working draft – Please don't circulate without permission

Council of the European Union. (2025, December 11). *'Pharma package': Council and Parliament reach a deal on new rules for a fairer and more competitive EU pharmaceutical sector* (Press release No. 1071/25). General Secretariat of the Council of the European Union.

European Commission. (2018). *Proposal for a regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU* (COM(2018) 51 final).

European Commission. (2023a). *Proposal for a regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use* (COM(2023) 193 final).

European Commission. (2023b). *Proposal for a directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use* (COM(2023) 192 final).

European Council. (2020). *European Council meeting (10 and 11 December 2020) – Conclusions* (EUCO 22/20).

European Federation of Pharmaceutical Industries and Associations. (2022). *Medicine shortages: EFPIA proposal for action*.

European Parliament. (2020). *European Parliament resolution of 10 July 2020 on the EU's public health strategy post-COVID-19 (2020/2691(RSP))*.

Exadaktylos, T. (2023). Multiple streams in the public policymaking processes of the European Union. In N. Zahariadis, N. Herweg, R. Zohlnhöfer, & E. Petridou (Eds.), *A modern guide to the multiple streams framework* (pp. 326–344). Edward Elgar Publishing. <https://doi.org/10.4337/9781802209822.00027>

Goyal, N., Howlett, M., & Taihagh, A. (2021). Why and how does the regulation of emerging technologies occur? *Regulation & Governance*, 15, 1020–1034. <https://doi.org/10.1111/rego.12387>

Haas, E. B. (1958). *The uniting of Europe: Political, social, and economic forces 1950–1957*. Stanford University Press.

Hall, P. A. (1993). Policy paradigms, social learning, and the state: The case of economic policymaking in Britain. *Comparative Politics*, 25(3), 275–296. <https://doi.org/10.2307/422246>

Herweg, N. (2016). Explaining European agenda-setting using the multiple streams framework. *Policy Sciences*, 49(1), 13–33. <https://doi.org/10.1007/s11077-015-9231-z>

Herrington, N., & Coogan, J. (2011). Q methodology: An overview. *Research in Teacher Education*, 1(2), 24–28. <https://doi.org/10.15123/ucl.8604v>

Hix, S., & Høyland, B. (2011). *The political system of the European Union* (3rd ed.). Palgrave.

Hooghe, L., & Marks, G. (2009). A postfunctionalist theory of European integration. *British Journal of Political Science*, 39(1), 1–23. <https://doi.org/10.1017/S0007123408000409>

Hu, B., Guo, H., Zhou, P., & Shi, Z. L. (2021). Characteristics of SARS-CoV-2 and COVID-19. *Nature Reviews Microbiology*, 19(3), 141–154. <https://doi.org/10.1038/s41579-020-00459-7>

Kanavos, P., & Mossialos, E. (1999). Outstanding regulatory aspects in the European pharmaceutical market. *Pharmacoeconomics*, 15(6), 519–533. <https://doi.org/10.2165/00019053-199915060-00003>

This is a working draft – Please don't circulate without permission

Karokis-Mavrikos, V. (2025a). *Agenda-setting and policy adoption drivers in EU pharmaceutical policy: An EU-MSF account* [Doctoral thesis, University of Surrey]. University of Surrey Open Access Repository. <https://doi.org/10.15126/thesis.901662>

Karokis-Mavrikos, V. (2025). Policy networks and policy entrepreneurship in the EU. *European Policy Analysis*, Advance online publication, 1–29. <https://doi.org/10.1002/epa2.70030>

Kingdon, J. (1984). *Agendas, alternatives and public policies*. Little Brown.

Marks, J. G., Hooghe, L., & Blank, K. (1996). European integration from the 1980s. *Journal of Common Market Studies*, 34(3), 341–378. <https://doi.org/10.1111/j.1468-5965.1996.tb00577>.

Moravcsik, A. (1998). *The choice for Europe*. Cornell University Press.

Mullard, A. (2017). PRIME time at the EMA. *Nature Reviews Drug Discovery*, 16(4), 226–228. <https://doi.org/10.1038/nrd.2017.57>

O'Connor, K. (2013). Q methodology as a tool for committee governance research. *West European Politics*, 36(5), 1073–1087. <https://doi.org/10.1080/01402382.2012.749650>

Ockwell, D., Whitmarsh, L., & O'Neill, S. (2009). Reorienting climate change communication. *Science Communication*, 30(3), 305–327. <https://doi.org/10.1177/1075547008328969>

Olsen, J. P. (2001). Garbage cans, new institutionalism and the study of politics. *American Political Science Review*, 95(1), 191–198. <https://doi.org/10.1017/S0003055401000120>

Organization for Economic Co-operation and Development. (2020). *Health at a glance: Europe 2020*. OECD Publishing. <https://doi.org/10.1787/82129230-en>

Permanand, G., & Mossialos, E. (2005). The Europeanization of regulatory policy. In M. Steffen (Ed.), *Health governance in Europe* (pp. 49–80). Routledge. <https://doi.org/10.4324/9780203087094>

Pierson, P. (1996). The path to European integration. *Comparative Political Studies*, 29(2), 123–163. <https://doi.org/10.1177/001041409602900200>

Pierce, J. J., Giordano, L. S., Peterson, H. L., & Hicks, K. C. (2020). Common approaches for studying advocacy. *The Social Science Journal*, 59(1), 139–158. <https://doi.org/10.1016/j.soscij.2019.06.005>

Princen, S. (2013). Punctuated equilibrium theory and the European Union. *Journal of European Public Policy*, 20(6), 854–870. <https://doi.org/10.1080/13501763.2013.781822>

Richardson, J. (2001). *European Union: Power and policymaking* (2nd ed.). Routledge.

Risse, M. (2009). The right to relocation. *Ethics & International Affairs*, 23(3), 281–300. <https://doi.org/10.1111/j.1747-7093.2009.00218.x>

Schmitter, P. C. (2005). Ernst B. Haas and the legacy of neofunctionalism. *Journal of European Public Policy*, 12(2), 255–272. <https://doi.org/10.1080/13501760500043951>

Travis, R., & Zahariadis, N. (2002). A multiple streams model of U.S. foreign aid policy. *Policy Studies Journal*, 30(4), 495–514. <https://doi.org/10.1111/j.1541-0072.2002.tb02160.x>

Van Exel, N. J. A., & De Graaf, G. (2005). *Q methodology: A sneak preview*. Q Methodology.

This is a working draft – Please don't circulate without permission

von der Leyen, U. (2020). *State of the Union address 2020: Building the world we want to live in*.

von Malmborg, F. (2023). Combining the advocacy coalition framework and argumentative discourse analysis. *Politics & Policy*, 51(2), 222–241. <https://doi.org/10.1111/polp.12525>

Watts, S., & Stenner, P. (2012). *Doing Q methodological research*. SAGE Publications.

Weible, C. M. (Ed.). (2023). *Theories of the policy process* (5th ed.). Routledge.

Weible, C. M., & Schlager, E. (2016). The multiple streams approach at the theoretical and empirical crossroads. *Policy Studies Journal*, 44(1), 5–12. <https://doi.org/10.1111/psj.12143>

Weick, K. (2001). *Making sense of the organization*. Blackwell Business.

Webler, T., Danielson, S., & Tuler, S. (2009). *Using Q method to reveal social perspectives in environmental research*. Social and Environmental Research Institute.

World Health Organization. (2020). *WHO Director-General's opening remarks at the media briefing on COVID-19 – 11 March 2020*.

Zahariadis, N. (2013). Building better theoretical frameworks of the European Union's policy process. *Journal of European Public Policy*, 20(6), 807–816. <https://doi.org/10.1080/13501763.2013.781815>

Zahariadis, N., Herweg, N., Zohlnhöfer, R., & Petridou, E. (Eds.). (2023). *A modern guide to the multiple streams framework*. Edward Elgar Publishing.

Appendix Table 1: Illustrative Shuffled List of Statements for the Q-Methodology Exercise	
Statement	Policy Area
The future of EU HTA should rely on promoting robust and transparent standards for the benefit of EU patients. Hence, an expanded centralised procedure with mandatory uptake is necessary.	HTA
The Covid-19 pandemic has highlighted the need for more substantive EU involvement in public health matters.	Covid-19
The current EU-level reforms in pharmaceutical policy will not provide effective and lasting solutions to the challenges of access, affordability, AMR, unmet medical need, and health security unless substantial national policy reforms follow as well.	General Pharmaceutical Legislation
Harmonisation in EU HTA needs to primarily address issues of resources and expertise to prevent a “race to the bottom” in terms of evaluation standards.	HTA
The new EU HTA framework will lead to more favourable pricing and reimbursement decisions for patients and health systems.	HTA
The future of EU HTA should rely on promoting robust and transparent standards, which respond to the demands of EU citizens. Hence, member state discretion over the uptake of joint outputs is necessary.	HTA
The European Health Union has given rise to a framework for sustained public health security.	Covid-19
Lowering baseline market exclusivity and emphasising conditionality threatens to promote indicator-gaming, orienting pharmaceutical research exclusively towards regulatory-favourable products.	General Pharmaceutical Legislation
Recent reforms in EU pharmaceutical policy have been motivated by suboptimalities in the functioning of the internal market.	Sector
Decreasing the baseline regulatory protection period and expanding conditional exclusivity incentives can drive more focused innovation, addressing challenges like orphan diseases and AMR	General Pharmaceutical Legislation
Member States must have exclusive executive responsibilities over the EU HTA framework, including the development of methodologies, the selection of technologies, the execution of JCAs and JSCs, and horizon scanning.	HTA
The current priorities of the EU-level pharmaceutical policy respond to the demands of a pluralistic interest ecosystem.	Sector
Expanding Joint Clinical Assessments aims at reducing transactional costs, but the currently proposed framework will be overly burdensome for manufacturers and regulators.	HTA
A patient-centred, health system-oriented approach to innovation incentives should underpin the EU's future policy outputs.	General Pharmaceutical Legislation
EUnetHTA has provided the blueprint for HTA cooperation, smoothing the transition to mandatory Joint Clinical Assessment.	HTA

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Recent reforms in EU pharmaceutical policy have been motivated by changing health needs and disease profiles.	Sector
The joint procurement of vaccines should be the blueprint for EU pharmaceutical production and supply challenges in times of normalcy and crisis.	Covid-19
A globally competitive and resilient pharmaceutical innovation industry should be the EU's leading vehicle for responding to patients' needs.	General Pharmaceutical Legislation
To promote regulatory expediency and consistency, the EMA should have significant involvement in the coordination and execution of Joint Clinical Assessments.	HTA
Despite an ambitious scope, the functioning of HERA appears restricted to the realm of pharmaceutical stockpiling.	Covid-19
The best approach to contain high medicines' prices in the EU is to restrict pharmaceutical innovation incentives and promote the quicker entry of generics to the market.	General Pharmaceutical Legislation
The best approach to contain high medicines' prices in the EU is to promote regulatory and budgeting reforms at the member state level to improve the pricing and reimbursement process.	General Pharmaceutical Legislation
The new look of the EU pharmaceutical policy sector is likely to achieve high global competitiveness and high patient satisfaction.	Sector
The Covid-19 disruption reconfigured the ongoing policy agendas of the EU pharmaceutical policy sector.	Covid-19
There is a strong correlation between patent monopolies and the affordability and accessibility crises that many EU citizens face today.	General Pharmaceutical Legislation
There is a need to redefine "innovation" in the field of pharmaceuticals, focusing on added health value and addressing unmet medical needs.	General Pharmaceutical Legislation
Under the current patent and intellectual property exclusivities regime, pharmaceutical manufacturers can request any price at will.	General Pharmaceutical Legislation
The new EU HTA framework is insufficiently inclusive, excluding patients from the locus of decision-making.	HTA
The EU is currently pursuing an extended public health mandate through pharmaceutical policy outputs.	Covid-19

Appendix Table 1: Illustrative Shuffled List of Statements for the Q-Methodology Exercise – [thematic breakdown was not shown to participants]

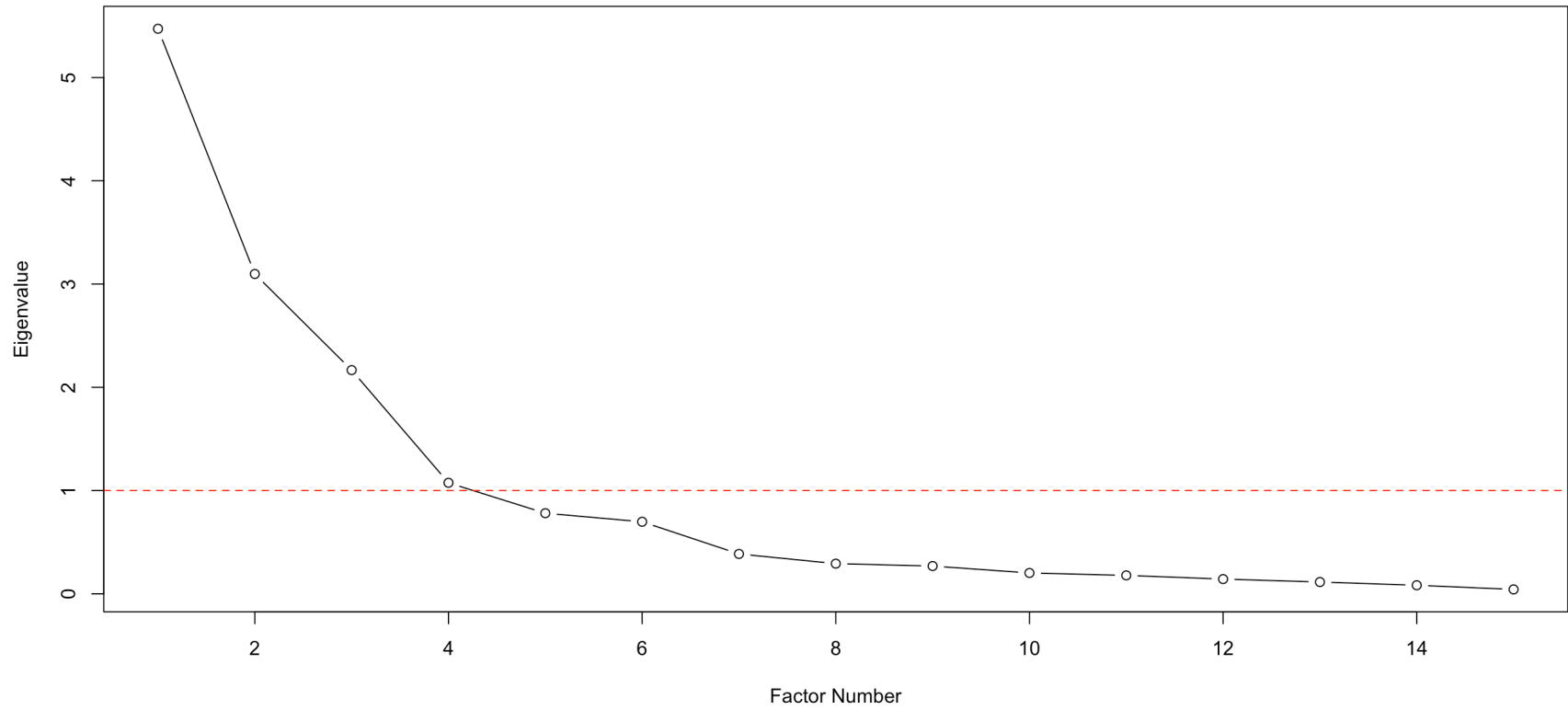
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Appendix Table 2: Q-sorts Correlation Matrix

Participant ID	Commission 1	Commission 2	Commission 3	Patients' Association 1	Patients' Association 2	Patients' Association 3	EUnetHTA	Pharmaceutical Industry 1	Pharmaceutical Industry 2	Pharmaceutical Industry 3	EP 1	EP 2	Council 1	Council 2	EMA
Commission 1	1.00	0.82	0.75	0.18	0.38	0.09	0.66	0.25	0.14	0.17	0.36	0.42	0.40	-0.04	0.74
Commission 2	0.82	1.00	0.63	0.20	0.38	0.20	0.58	0.30	0.27	0.29	0.43	0.45	0.38	0.14	0.81
Commission 3	0.75	0.63	1.00	0.15	0.32	0.10	0.67	0.05	0.01	-0.11	0.60	0.45	0.52	0.30	0.60
Patients' Association 1	0.18	0.20	0.15	1.00	0.70	0.66	0.09	0.08	0.13	-0.01	0.61	0.28	0.31	-0.10	0.19
Patients' Association 2	0.38	0.38	0.32	0.70	1.00	0.75	0.19	-0.06	0.09	-0.08	0.67	0.46	0.31	-0.16	0.43
Patients' Association 3	0.09	0.20	0.10	0.66	0.75	1.00	-0.11	-0.31	-0.06	-0.18	0.46	0.45	0.16	-0.08	0.13
EUnetHTA	0.66	0.58	0.67	0.09	0.19	-0.11	1.00	0.40	0.19	0.04	0.41	0.38	0.59	0.17	0.61
Pharmaceutical Industry 1	0.25	0.30	0.05	0.08	-0.06	-0.31	0.40	1.00	0.80	0.74	0.05	-0.04	0.03	-0.19	0.43
Pharmaceutical Industry 2	0.14	0.27	0.01	0.13	0.09	-0.06	0.19	0.80	1.00	0.79	0.15	-0.04	-0.09	-0.14	0.40
Pharmaceutical Industry 3	0.17	0.29	-0.11	-0.01	-0.08	-0.18	0.04	0.74	0.79	1.00	-0.06	-0.20	-0.22	-0.23	0.31
EP 1	0.36	0.43	0.60	0.61	0.67	0.46	0.41	0.05	0.15	-0.06	1.00	0.35	0.46	0.22	0.36
EP 2	0.42	0.45	0.45	0.28	0.46	0.45	0.38	-0.04	-0.04	-0.20	0.35	1.00	0.52	0.24	0.42
Council 1	0.40	0.38	0.52	0.31	0.31	0.16	0.59	0.03	-0.09	-0.22	0.46	0.52	1.00	0.32	0.30
Council 2	-0.04	0.14	0.30	-0.10	-0.16	-0.08	0.17	-0.19	-0.14	-0.23	0.22	0.24	0.32	1.00	0.01
EMA	0.74	0.81	0.60	0.19	0.43	0.13	0.61	0.43	0.40	0.31	0.36	0.42	0.30	0.01	1.00

Appendix Table 2: Q-sorts Correlation Matrix

Scree Plot of Eigenvalues



Appendix Figure 1: Scree Plot of Eigenvalues

Appendix Table 3 – Factor Arrays			
Statements	Factor 1 (The Institutional Viewpoint)	Factor 2 (The Patients Viewpoint)	Factor 3 (The Pharmaceutical Industry Viewpoint)
A globally competitive and resilient pharmaceutical innovation industry should be the EU's leading vehicle for responding to patients' needs	0	-2	3
A patient-centred, health system oriented, approach to innovation incentives should underpin the EU's future policy outputs	3	3	2
Under the current patent and intellectual property exclusivities regime, pharmaceutical manufacturers can request any price at will	-2	2	-3
There is a strong correlation between patent monopolies and the affordability and accessibility crises that many EU citizens face today	0	2	-3
The best approach to contain high medicines' prices in the EU is to restrict pharmaceutical innovation incentives and promote the quicker entry of generics to the market	0	1	-3
The best approach to contain high medicines' prices in the EU is to promote regulatory and budgeting reforms at the member state level, to improve the pricing and reimbursement process	-2	-1	3
There is a need to redefine "innovation" in the field of pharmaceuticals, focusing on added health value and addressing unmet medical need	2	3	0
Decreasing the baseline regulatory protection period and expanding conditional exclusivity incentives can drive more focused innovation, addressing challenges like orphan diseases and AMR	2	1	-1
Lowering baseline market exclusivity and emphasising conditionality threatens to promote indicator-gaming, orienting pharmaceutical research exclusively towards regulatory-favourable products	-2	-2	1
EUnetHTA has provided the blueprint for HTA cooperation, smoothing the transition to mandatory Joint Clinical Assessment	1	0	1
Harmonisation in EU HTA needs to primarily address issues of resources and expertise to prevent a "race to the bottom" in terms of evaluation standards	1	2	1

Expanding Joint Clinical Assessments aims at reducing transactional costs, but the currently proposed framework will be overly burdensome for manufacturers and regulators	-2	-3	2
Member States must have exclusive executive responsibilities over the EU HTA framework, including the development of methodologies, the selection of technologies, the execution of JCAs and JSCs, and horizon scanning.	-1	-3	-2
The current priorities of the EU-level pharmaceutical policy respond to the demands of a pluralistic interest ecosystem	1	-2	1
The future of EU HTA should rely on promoting robust and transparent standards for the benefit of EU patients. Hence, an expanded centralised procedure with mandatory uptake is necessary	3	2	2
The future of EU HTA should rely on promoting robust and transparent standards, which respond to the demands of EU citizens. Hence, member state discretion over the uptake of joint outputs is necessary	-1	-3	-2
The Covid-19 pandemic has highlighted the need for more substantive EU involvement in public health matters	2	1	0
The European Health Union has given rise to a framework for sustained public health security	1	-1	-1
EU-level policies during the Covid-19 response consisted of limited-scope, symbolic interventions	-3	-2	-1
The new EU HTA framework will lead to more favourable pricing and reimbursement decisions for patients and health systems	3	-1	1
The new EU HTA framework is insufficiently inclusive, excluding patients from the locus of decision-making	-3	3	-1
Recent reforms in EU pharmaceutical policy have been motivated by changing health needs and disease profiles	1	1	2
Recent reforms in EU pharmaceutical policy have been motivated by suboptimalities in the functioning of the internal market	0	0	0
To promote regulatory expediency and consistency, the EMA should have significant involvement in the coordination and execution of Joint Clinical Assessments	0	-1	0
Despite an ambitious scope, the functioning of HERA appears restricted to the realm of pharmaceutical stockpiling	-3	0	0
The EU is currently pursuing an extended public health mandate through pharmaceutical policy outputs	0	1	0
The joint procurement of vaccines should be the blueprint for EU pharmaceutical production and supply challenges in times of normalcy and crisis	-1	0	-2

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The current EU-level reforms in pharmaceutical policy will not provide effective and lasting solutions to the challenges of access, affordability, AMR, unmet medical need and health security, unless substantial national policy reforms follow as well	-1	0	3
The new look of the EU pharmaceutical policy sector is likely to achieve high global competitiveness and high patient satisfaction	2	-1	-2
The Covid-19 disruption reconfigured the ongoing policy agendas of the EU pharmaceutical policy sector	-1	0	-1

Appendix Table 3: Factor Arrays