Policy Networks and Policy Entrepreneurship in the EU: Explaining Structural Policy Change in Pharmaceutical Innovation Incentives and HTA

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Abstract: *The EU is currently experiencing its longest period without a Treaty revision since Eurosclerosis, having evolved into political system with a distinctive multi-level governance architecture. Therefore, EU-level policy change requires moving beyond the dichotomous focus of European integration theories and adapting the tools of policy process research to the EU level. This study applies a modified iteration of the Multiple Streams Framework – the EU-MSF – to two structural reforms in EU pharmaceutical policy: the revision of the General Pharmaceutical Legislation and the establishment of the new EU HTA framework. Drawing on primary data, the study examines the impact of policy network integration on the nature of favourable policy alternatives and the success of policy entrepreneurship strategies. The findings indicate that the level of policy network integration shapes the relative importance of technical feasibility and value acceptability and, in turn, informs policy entrepreneurship strategies, such as 'snooker-tactics' and 'recoil-tactics'.*

Keywords: Policy Entrepreneurship, Policy Networks, EU-MSF, HTA, General Pharmaceutical Legislation

No conflict of interest to declare

Introduction

The EU is currently experiencing its longest period without a Treaty revision since the era of *Eurosclerosis* (Dinan, 2008; Giersch, 1985). Nevertheless, unlike the two decades of institutional stagnation between 1965 and 1986, which were fuelled by doubts on the future of European cooperation, the current period of 'constitutional' stability, since the Treaty of Lisbon (2009), reflects the EU's evolution into a *sui generis* political system. Today, the EU has far eclipsed its original status as an international organisation and has developed into a political system without a state (Hix & Høyland, 2011), with a unique multi-level governance architecture (Hooghe & Marks, 2009). Consequently, policy change, including structural reforms that shift both the goals and the means of policy paradigms (Hall, 1993), increasingly takes place through the Ordinary Legislative Procedure (OLP).

In this evolving context, understanding policy change requires moving beyond the Theories of European Integration and leveraging the meso-level focus of policy process research, which can uniquely illuminate the impact of ideas, interests and institutions on transformative policy outputs (Weible, 2023; Hall, 1997). This paper intends to contribute to the young but emerging EU policy process research agenda, focusing on the impact of policy networks on the nature of favourable policy alternatives and the success of policy entrepreneurship strategies.

Specifically, this study evaluates two recent instances of structural reform in EU pharmaceutical policy – the revision of the General Pharmaceutical Legislation and the establishment of the new EU HTA framework – through a modified iteration of the Multiple Streams Framework, the EU-MSF. The analysis concludes that successful policy entrepreneurship in highly integrated networks depends on reconfiguring value acceptability. In the case of the revision of the General Pharmaceutical Legislation, this was achieved through 'snooker-tactics' policy entrepreneurship, as previously marginalised policy entrepreneurs disrupted a long-established policy monopoly. By contrast, in weakly integrated networks, successful policy entrepreneurship is more heavily conditional on technical feasibility. In the case of the new EU HTA framework, the Commission deployed 'recoil-tactics' policy entrepreneurship by identifying feasible policy alternatives through the strategic use of the Roadmap/Inception Impact Assessment and public consultation, thereby shaping decision-making outcomes.

The paper is structured as follows. First, it reviews the key theoretical lenses for the study of EU-level policy change, emphasising the need for systematic EU policy process research. It then presents the EU-MSF, along with the paper's hypotheses and analytical strategy. Next, the analysis evaluates the two case studies, before the conclusion outlines the implications for EU studies, policy entrepreneurship, and crisis and multi-level governance.

Explaining EU-level Policy Change

Throughout the EU's 70-year history, research on EU-level policy developments has primarily focused on the Union's supranational governance architecture. Neofunctionalist accounts (Schmitter, 2005; Haas, 1958) attribute the transfer of competences to EU institutions across sectors to consecutive spillovers, driven by collective economic and transactional gains. In contrast, Liberal Intergovernmentalism explains EU-level stability and stasis through the calculated, collective decision-making of rationally motivated Member States (Moravcsik, 1998). Federalist, historical institutionalist, and constructivist accounts emphasise the roles of political leadership, critical junctures, and normative feedback loops, respectively (Risse, 2009; Burgess, 2000; Pierson, 1996). Meanwhile, postfunctionalism highlights identity perceptions and national party characteristics as key drivers of integration and disintegration within the EU's multi-level governance environment (Hooghe & Marks, 2009; Marks et al., 1996).

While this body of scholarship has been successful in explaining the EU's macro-political evolution across successive Treaty revisions, it has limited analytical capacity in capturing the drivers of structural policy reforms within the EU's current institutional landscape. In recent years, particularly since the Treaty of Lisbon (2009), scholars have increasingly converged in viewing the EU as a distinct political system (Hix & Høyland, 2011). As a result, 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 EU-level policy change – much like in national political systems (Zahariadis, 2013).

To this end, scholars have increasingly sought to extend and adapt policy process frameworks to the EU context. Both the Advocacy Coalition Framework (ACF) and the Punctuated Equilibrium Theory (PET) have seen a higher volume of EU-level applications since the 2010s, focusing on venues, policy-oriented learning and policy subsystem evolution in health, budgeting and climate and energy policies (von Malmborg, 2023; Brooks, 2018; Benson & Russell, 2015; Princen, 2013; Citi, 2013).

While EU-level policy process accounts remain limited, the scholarship on the Multiple Streams Framework (MSF) and policy entrepreneurship arguably provide the most promising foundation for systematic policy process research at the EU level to date. Zahariadis (2008), Ackrill et al. (2013), and Exadatylos (2023) have emphasised the theoretical transferability of the MSF to the EU level, while Borrás and Radaelli (2011), Bache (2012), and Goyal et al. (2021) have applied the MSF to quality-of-life policymaking, the emergence of the Lisbon Strategy, and the adoption of the EU General Data Protection Regulation, respectively. Similarly, Braun (2009), Palmer (2014) and Thierse (2017) have explored policy entrepreneurship in environmental policy case studies, focusing on both institutional and non-institutional actors.

Across these applications, scholars have consistently highlighted the need for contextual adaptations in the analytical tools and expectations of both the MSF and the policy entrepreneurship literature to accommodate the particularities of the EU policy process. However, a systematic programme of theory

building and testing has yet to emerge. Herweg (2016) offers one of the most detailed EU-level MSF applications to date, focusing on European gas regulation, while Karokis-Mavrikos (2025) introduces the 'EU-MSF,' a comprehensive adaptation of the framework to the modern configuration of the EU political system. This paper adopts the analytical approach of the EU-MSF developed by Karokis-Mavrikos (2025), focusing, first, on hypotheses concerning the impact of policy networks on the nature of successful policy ideas and, second, on the patterns of strategic policy entrepreneurship. In doing so, it aims to advance a systematic EU-MSF research agenda.

The EU-MSF

The MSF draws on the 'garbage can model' of organisational choice (Cohen, March and Olsen, 1972) to study policymaking under conditions of ambiguity – that is when multiple ways of interpreting the same circumstances exist (Zahariadis et al., 2023; Kingdon, 1984). 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, in Zahariadis, 2007), exhibiting fluidity in stakeholder participation, opacity in organisational capacity, dynamic actor preferences, and high procedural complexity. As the MSF operationalizes institutions only implicitly – thus reducing contextual bias and encouraging transferability (Cairney and Heikkila, 2014) – the EU provides a highly suitable setting for insightful MSF applications.

The EU-MSF, as applied in this study, retains the MSF's core hypothesis: *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.*

Nevertheless, necessary adaptations are introduced where the functional equivalents of the MSF's analytical components cannot be identified in the EU political system, to enhance the validity and reliability of the analysis.

The problem stream has consistently been regarded as the most readily adaptable to the EU context in scholarship (Herweg, 2017; Ackrill et al., 2013; Zahariadis, 2008). According to the MSF, three types of mechanisms – *alarming deteriorations in indicators*, *policy feedback*, and *focusing events* – can mobilize policymakers' attention to emerging problems. While all three are well-documented within the EU political system, the multi-level governance architecture introduces an additional layer of complexity by making the direction of attention mobilization a crucial factor in assessing the problem stream's ripeness. As such, in the case of *indicators* and *policy feedback*, the EU-MSF identifies *upward vertical* mechanisms, which operate from the national to the EU level; *downward vertical* mechanisms, which function from the international to the EU level; and *horizontal* mechanisms, which emerge across venues or policy subsystems at the EU level.

In contrast to the problem stream, the politics stream has been identified as the one requiring the most far-reaching adaptations (Herweg, 2016). The politics stream conceptualizes the political willingness and

determination necessary for policy change (Kingdon, 1984). In national-level MSF accounts, it is shaped by *legislative or administrative turnover*, *organized interest group action*, and the *national mood* (Herweg et al., 2018). However, in the EU context, the impact *of legislative turnover* remains debated, as decision-making in the European Parliament (EP) frequently relies on ad hoc coalitions, and the two largest parties tend to vote together on most issues (Herweg, 2016; Decker & Sonnicksen, 2011). Meanwhile, the existence of a 'European mood' is also contested due to measurement difficulties and limited public engagement in EU-level affairs (Pannico, 2020; Beyers et al., 2018; Herweg, 2016).

As such, the EU-MSF proposes that evaluating the ripeness of the politics stream is best achieved through an assessment of political narratives, as communicated by the three EU institutions participating in the Ordinary Legislative Procedure (OLP): the Council of the European Union, the European Parliament, and the European Commission. Drawing on insights from European integration scholarship, the EU-MSF posits that the discourse of each of these three institutions aligns with a distinct perception of the EU public.

The Commission is expected to serve a 'functional' perception of the EU public, prioritizing technocratic expertise, process simplification, and the reduction of transactional costs. The EP, by contrast, is expected to embody a 'popular' perception of the EU public, emphasizing democratic accountability and the mitigation of social, political, and economic inequalities. Finally, the Council is expected to embody a 'ruling' perception of the EU public, conflating national public preferences with national interests as articulated by government officials and prioritising national strengthening through monetary and regulatory benefits. As such, in the study of EU-level public policy change, political willingness or determination is evaluated through the degree of compatibility between policy alternatives and institutional narratives.

The policy stream, which serves as the focus of this study, captures the emergence of transformative policy alternatives and provides the primary operating space for policy entrepreneurs. MSF scholarship identifies *technical feasibility, value acceptability* and *resource adequacy* as essential criteria for reformative ideas to survive and gain traction. While early MSF accounts (Kingdon, 1984) proposed an omnipresent softening process until ideas sufficiently met the three criteria, more recent refinements have connected the nature and scope of successful policy alternatives to the level of policy network integration.

Specifically, Zahariadis (2003), drawing on insights from the scholarship on policy communities and policy networks (Rhodes and Marsh, 1992; Rhodes, 1990; Jordan, 1990), has proposed that in highly integrated networks – characterised by a small number of participants, strong barriers to entry, a consensual mode of interaction, and high administrative capacity – policy alternatives are likely to face prolonged softening-up, resulting in frequent yet incremental reforms. By contrast, less integrated networks – characterised by a large number of participants, low barriers to entry, a competitive mode of interaction, and low administrative capacity – are more likely to produce radical policy alternatives, albeit sporadically.

Drawing on this literature, the EU-MSF posits that the degree of policy network integration is central to understanding both the nature of successful policy alternatives and the pace of their emergence within

the EU's multi-level governance architecture. Specifically, in the EU political system, the following path can be expected (Figure 1):

In less-integrated, highly multi-level network settings – where institutional and procedural infrastructure for debating ideas at the EU level is absent or underdeveloped – EU-level policy alternatives are likely to require persistent vertical and horizontal softening up and long incubation periods. Consequently, they are expected to exhibit the properties of the *gradualist* quadrant. However, as successful alternatives are founded on consensus, they are also likely to involve delegation or the creation of new institutions at the EU level. This transition is likely to shift the mode and tempo of ideas into the *quantum* quadrant, as procedural efficiency and new institutional capacities encourage rapid mutation. Nonetheless, as stakeholder interaction becomes systematised, polarising policy alternatives are likely to face increasing scrutiny, often ex ante. Consequently, both the mode and tempo of policy alternatives are expected to shift towards the *convergent* quadrant, where the pace of decision-making remains high, but policy ideas are progressively softened. Eventually, mutation may re-emerge, albeit at a much slower pace, requiring (*emergent quadrant)*.

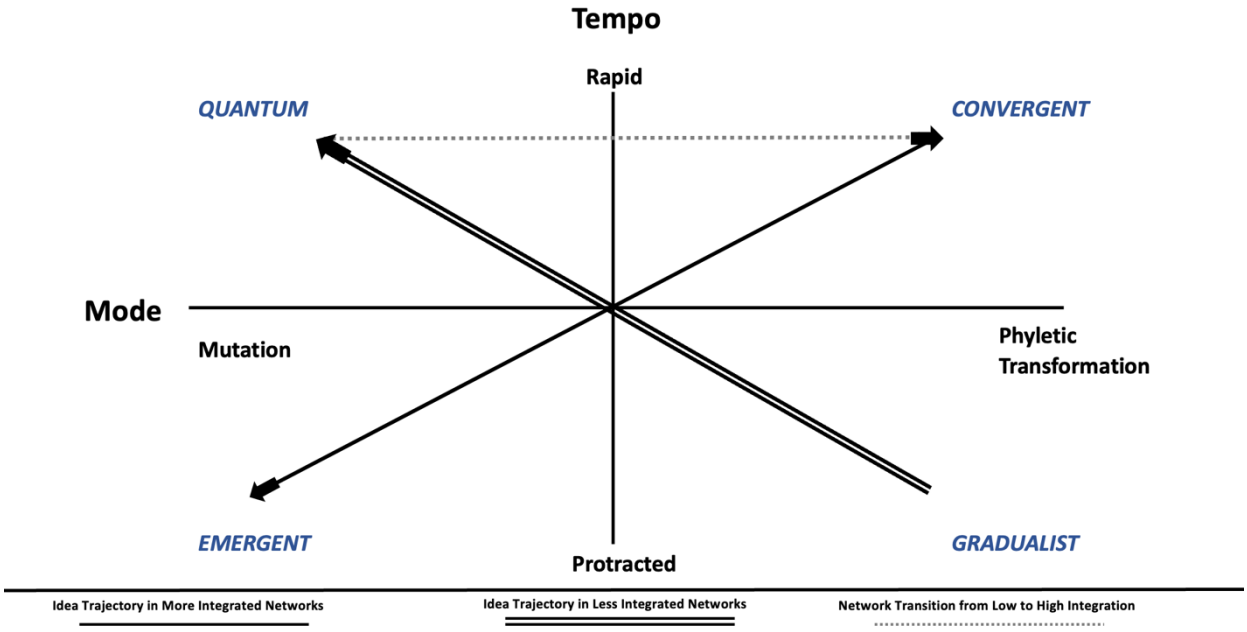


Figure 1: Network Integration and Idea Trajectory in the EU-MSF

Throughout this process, networks can transition from lower to higher levels of integration. Crucially, depending on the relative degree of policy network integration, the success of transformative policy alternatives is likely to hinge on different criteria. *In less integrated networks, technical feasibility is expected to prove more decisive than value acceptability*. The competitive mode of interaction produces persistent conflict unless policy alternatives promise improvements in the network's administrative capacity, typically through delegation or the creation of new institutions at the EU level. In more integrated networks, where policy outcomes are more likely to be redistributive, value acceptability is expected to

outweigh technical feasibility. Higher administrative capacity reduces ambiguity regarding organisational capabilities (Zahariadis, 2003) and shifts the focus toward overcoming value-laden vetoes posed by both formal and informal stakeholders.

Last, as in national settings, windows of opportunity in the EU-MSF may open in either the problem or the politics stream, driven by the respective stream mechanism – most notably focusing events and shifts in political narratives.

Research Design

This study adopts a process-tracing approach, guided by the EU-MSF, to examine two recent cases of structural policy change in EU pharmaceutical policy: the revision of the General Pharmaceutical Legislation and the new HTA framework (European Parliament, 2024a, 2024b; European Commission, 2023a, 2023b). The former refers to the impending overhaul of the EU's rules for obtaining approval to market innovative medicines in the EU single market and the corresponding incentives provided to manufacturers. The latter involves the establishment of an EU-level institutional framework for HTA, including a system of Joint Clinical Assessments (JCAs), following three decades of voluntary collaboration.

This study aims to evaluate the impact of policy network integration on the drivers of EU-level structural policy change, with a particular focus on the effectiveness of policy entrepreneurship strategies. To this end, as will be discussed in the following sections, the two case studies capture concurrent instances of transformative policy change within the same sector, albeit in domains characterised by markedly different levels of policy network integration. Accordingly, the analysis tests the two EU-MSF hypotheses introduced earlier and explores variations in policy entrepreneurship patterns across the two illustrative cases.

> **H1:** In highly integrated policy networks, the success of policy alternatives proposing structural policy change depends more on satisfying value acceptability than technical feasibility.
>
> **H2:** In weakly integrated policy networks, the success of policy alternatives proposing structural policy change depends more on satisfying technical feasibility than value acceptability.

The study is informed by primary sources in the form of framework-driven document analysis and 40 elite interviews with policy stakeholders involved in the initiatives under study. Document analysis encompasses binding and non-binding EU acts, European Commission strategies, roadmaps and impact assessments, contributions to public consultations, opinions from European Parliament and Council committees, and reports from the European Medicines Agency (EMA). It also includes position papers, opinions, annual reports, and press releases by non-institutional stakeholders, such as international organisations and pharmaceutical policy interest groups.

Interviews were conducted between January 2022 and June 2023, with the participation of EU policymakers and non-institutional policy stakeholders (Table 1), as selected by a combination of purposive

and snowball sampling (response rate: 53%) (Parker et al., 2019; Etikan et al., 2016). They were semi-structured, guided by the analytical axes of the EU-MSF, lasted an average of 30 minutes and were conducted both online and in-person. Table 1 presents a breakdown of the interview participants by affiliation. For the purposes of this study, interviewees are explicitly identified by their role and affiliation only when direct quotations are used.

Table 1: Distribution of Interviewees by Organisational Affiliation	
Affiliation	**Number of Participants**
European Commission (DG SANTE and DG HERA)	6
Patients' Associations	5
Associations of Pharmaceutical Manufacturers	6
Public Affairs Representatives of the Pharmaceutical Industry	1
European Parliament (Representatives and Support Staff)	5
European Council (Representatives, Permanent Representations and Committee Staff)	5
European Medicines Agency (EMA)	4
EUnetHTA	2
Representatives from National Medicines' Agencies and National HTA Committees of EU Member States	5
World Health Organisation (WHO)	1

Table 1: Distribution of Interviewees by Organisational Affiliation

Analysis:

‘Snooker-tactics’ Policy Entrepreneurship: The Revision of the General Pharmaceutical Legislation:

Overview

The EU’s General Pharmaceutical Legislation consists of a series of Regulations and Directives, originally introduced during the 1990s and 2000s that establish the regulatory framework for obtaining approval to develop and market medicines within the EU Single Market (European Commission, 2021). On the one hand, the General Pharmaceutical Legislation sets the criteria for approving medicinal products as safe for circulation in EU Member States – a process administered by the European Medicines Agency (EMA), (Regulation (EC) No 726/2004; Directive 2001/83/EC). On the other hand, since pharmaceutical development is a high-cost, low-success endeavour, both General and Specific legislation lay down regulatory provisions that link market authorisation to a series of innovation incentives, including Intellectual Property (IP) rights, market exclusivity, and data protection (Regulation (EC) No 469/2009; Regulation (EC) No 1901/2006; Regulation (EC) No 141/2000).

While innovative medicines benefit from 20 years of commercial exclusivity under the European Patent Convention (EPC), developers spend a significant portion of this patent period – often more than half – conducting clinical trials to ensure the medicine’s safety and efficacy. To this end, since 1992, the EU has introduced the “Supplementary Protection Certificate” (SPC), a unique extension of IP protection for medicines that aims to restore up to 5 years of “effective” patent life (i.e., after the product has entered the market) (Regulation (EEC) No 1768/92, now Regulation (EC) No 469/2009).

Moreover, while patents protect innovative medicines as inventions, their scope does not extend to the preclinical and clinical data generated during the product’s development. To protect manufacturers’ investments and encourage innovation, the General Pharmaceutical Legislation provides 8 years of regulatory data protection from the date of market authorisation, followed by 2 years of market protection – with a possible extension of an additional year if the medicine receives a new therapeutic indication that offers significant clinical benefit compared to existing therapies (known as the “8+2+1 formula”). During this period, competitors, namely generic and biosimilar developers, cannot cross-reference the clinical data (for 8 years) or market generic versions of the product (for 2+1 years) (Directive 2004/27/EC).

Last, additional innovation incentives are offered for special categories of medicinal products, specifically those that obtain orphan and paediatric indications. Orphan medicines are intended for diseases without satisfactory treatments, affecting no more than 5 in 10,000 people, where investment would not be financially justified without incentives (Regulation (EC) No 141/2000). To this end, they benefit from 10 years of standard market exclusivity, compared to the baseline duration of 8 years. Furthermore, medicinal

products that complete a Paediatric Investigation Plan (PIP) are rewarded with a 6-month extension of the SPC or 2 additional years of market exclusivity in the case of orphan medicines, to incentivise R&D for the benefit of children.

Error! Reference source not found. Figure 2 offers a visual representation of the IP, market and data protection system for innovative medicines under the General Pharmaceutical Legislation.

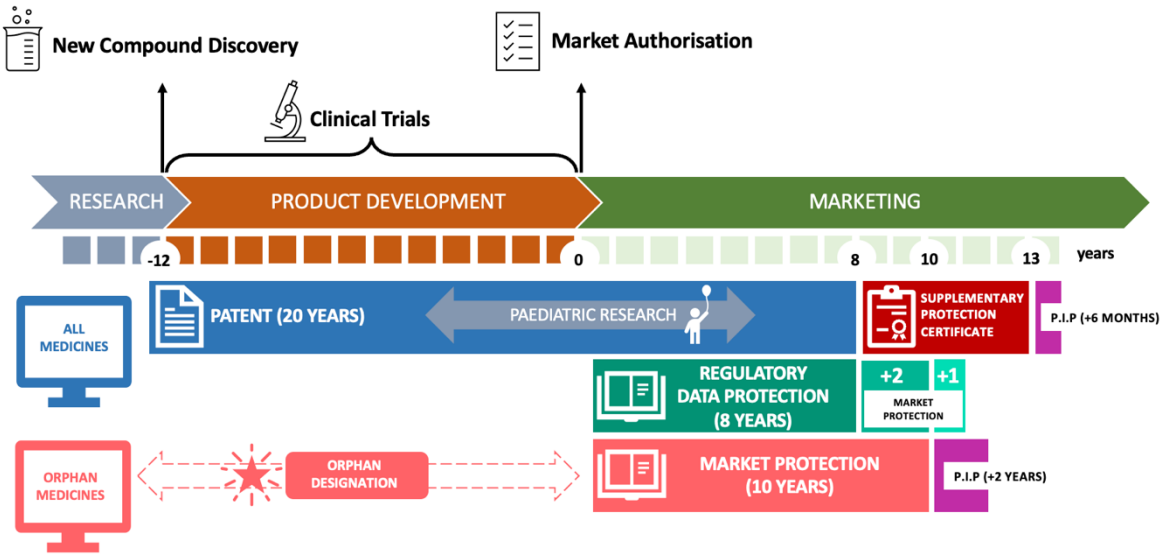


Figure 2: IP, Market and Data Protection for Innovative Medicines as provisioned by the EU's General and Specific Pharmaceutical Legislation

Nevertheless, since the mid-2010s, both the provisions and objectives of the General Pharmaceutical Legislation have come under comprehensive scrutiny. On 25 April 2023, European Commission Vice-President Margaritis Schinas announced the "most complex, neuralgic, epic, big package we have prepared in the area of health throughout our mandate," aiming to revamp "one of the oldest pieces of legislation, about 20 years old" (European Commission, 2023c). Upon the conclusion of the first von der Leyen Commission's term (2019–2024), the revision of the General Pharmaceutical Legislation has been endorsed by the European Parliament, with the Council's position pending to conclude the legislative process. The following sections explain how the policy paradigm on EU pharmaceutical innovation incentives shifted towards lower and more highly conditional data and market protection, highlighting the connection between policy network integration and successful policy entrepreneurship strategies.

The EU Market Authorisation Policy Network

Market authorisation was the first domain of pharmaceutical policy to experience European-level policy activity, beginning as early as 1965 with Directive 65/65/EEC. Nevertheless, until the 1990s, the network remained weakly integrated due to the absence of institutionalised interdependence between stakeholders. Throughout this period, it exhibited the characteristics of the *gradualist* quadrant (Figure 3), with policy alternatives emerging at a slow pace and proposing only incremental (phyletic) EU-level policy changes.

During the late 1980s, the demands of the Single Market transition, reinforced by technological advancements and increased competition, created an unprecedented window of opportunity to redesign the authorisation process for medicines among EU Member States (Gambardella et al., 2000; Commission of the European Communities, 1994). This process culminated in the adoption of the General Pharmaceutical Legislation, as outlined in the previous section, with the European Commission and organised representatives of the pharmaceutical innovation industry emerging as key policy entrepreneurs.

Leading the former were the Directorates-General (DGs) for the Internal Market and Industrial Affairs, tasked with overseeing the single-market transition (Permanand, 2002). Meanwhile, spearheading the latter was the European Federation of Pharmaceutical Industries and Associations (EFPIA), founded in 1978 to represent the pharmaceutical innovation industry at the EC level. By the late 1980s, EFPIA had established a strong foothold within the European arena, particularly when compared to other non-institutional stakeholders such as patients' associations or the generics industry. Consequently, the establishment of the General Pharmaceutical Legislation focused on developing attractive regulatory processes for future suppliers and regulators within the Single Market. During this period, the EU policy network for market authorisation transitioned from the *gradualist* to the *quantum* quadrant (Figure 3), characterised by the rapid emergence of structural policy reforms (mutation).

The era of "Specific Legislation", in the 2000s and 2010s, marked the network's final transition to date, with incremental transformations in rapid pace (*convergent* quadrant) reinforcing the policy outlook of the General Pharmaceutical Legislation. Under the current status quo, the EU policy network for market authorisation has been characterised by stable patterns of participation, increased institutional and procedural interdependence among members, and high barriers to entry. Within this context, according to the EU-MSF (H1), achieving transformative policy change requires prolonged deliberation, focused on reconfiguring value acceptability. As such, the impending revision of the General Pharmaceutical Legislation has placed the policy network in the *emergent* quadrant, heading towards mutation after decades of paradigm stability (Figure 3).

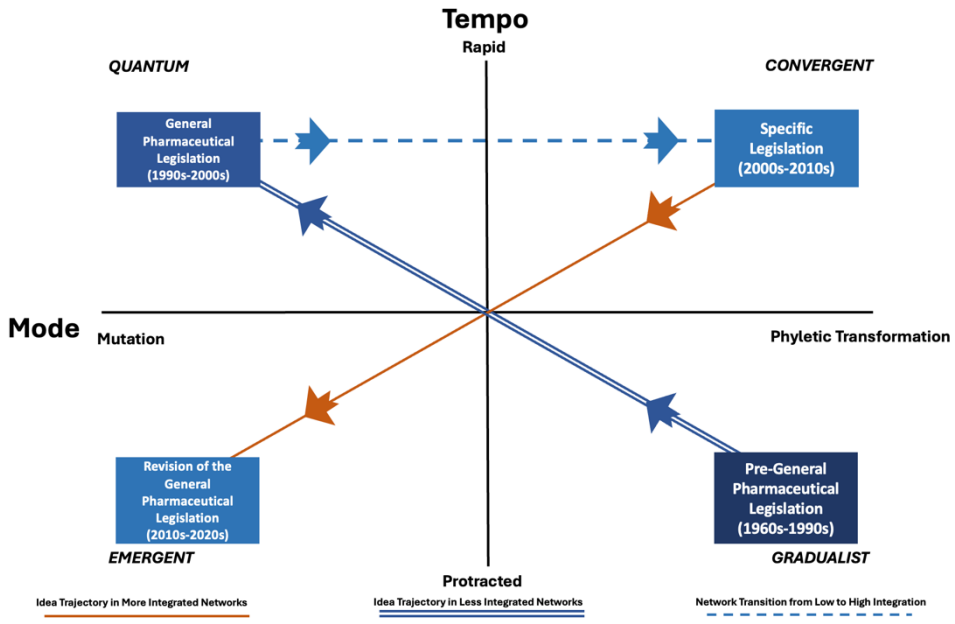


Figure 3: Evolution in the Level of Integration of the EU Policy Network for Market Authorisation

The Problem Stream

The ripening of the problem stream in the case of the revision of the General Pharmaceutical Legislation began in the aftermath of the European Sovereign Debt Crisis (or Eurozone crisis, for short). The prolonged economic downturn faced by Eurozone Member States from 2009 to the mid-2010s – a systemic focusing event – showed sustained impact on problem emergence. As such, attention mobilisation was driven both by the immediate economic shock and the long-term austerity policies deployed in response, in a process beginning with vertical and concluding with horizontal mechanisms.

The Eurozone crisis forced emergency national measures across the EU, increasing private and industry contributions to national budgets in an effort to offset cuts in public spending (Vogler et al., 2011). Over time, "the combination of decreased public investment, increased consumer burden, and high profit volatility for pharmaceuticals magnified socioeconomic inequalities in access to treatments" and placed strains on the availability of medicines across EU Member States (*Permanent Representation official*). However, as pricing and reimbursement had remained outside the remit of EU policymaking, the persistence of domestic hardships prompted EU Member States to place the General Pharmaceutical Legislation under unprecedented scrutiny in the workings of the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO).

In 2016, led by the Dutch Presidency, EPSCO stressed that "access to effective and affordable essential medicines" is becoming "endangered by very high and unsustainable price levels", for which "governments have sometimes limited influence". According to the Member States, the EU's regulatory environment for medicines gave rise to a series of adverse outcomes, including "when new products are not introduced to

national markets for business economic strategies"; "market withdrawal of products that are out-of-patent"; an "increasing trend of marketing authorisation of new medicinal products for small indications"; and "companies seeking very high prices while the added value of […] products is not always clear" (Council of the European Union, 2016).

Following the 2016 Council conclusions, horizontal attention mobilisation mechanisms broadened the scrutiny of the General Pharmaceutical Legislation within the EU arena, linking the challenges of affordability and accessibility faced by EU patients to *unmet medical need*[1]. This process involved contributions from the European Commission and the European Parliament (European Parliament, 2017), as well as the catalytic influence of patients' associations to the problem stream's ripening.

By the late 2010s, EU patients had gained established and organised representation within the pharmaceutical policy sector, through both disease-specific and cross-cutting organisations like the European Patients' Forum (EPF) and the European Public Health Alliance (EPHA). This marked a significant departure from the 1980s and 1990s, during the lead-up to the General Pharmaceutical Legislation, when patients' interests were primarily communicated through umbrella consumer organisations, such as the European Consumers Organisation (BEUC).

Within the problem stream, the presence of a strong patients' voice provided a unique source of policy feedback. As strongly stated by EPHA, the 2016 Council conclusions "took many by surprise and surely made drug manufacturers very uncomfortable" by highlighting "the elephant in the room: the correlation between patent monopolies and the affordability and accessibility crises that many Europeans face today". From the perspective of patients, health professionals and public health stakeholders, which EPHA represents, the "incentives originally put in place to promote innovation in the field of rare diseases" had increasingly become "abused to maximise profit" over time (Natsis, 2017).

Echoing the emerging unrest, the European Commission initiated a series of consultative activities between 2016 and 2021. By 2021, the Commission identified five categories of problems that future policymaking related to the General Pharmaceutical Legislation would need to address, drawing on inputs to the problem stream over the previous half-decade. They concerned *unmet medical need and market failures for non-orphan and paediatric medicines*, *unequal access to affordable medicines across the EU*, *regulatory rigidity in adapting to innovation demands, supply chain vulnerabilities, and administrative inefficiencies.* Table 2 summarises the identified problems in more detail.

[1] "An unmet medical need is a condition whose treatment or diagnosis is not addressed adequately by available therapy. An unmet medical need includes an immediate need for a defined population (i.e., to treat a serious condition with no or limited treatment) or a longer-term need for society (e.g., to address the development of resistance to antibacterial drugs)". (U.S. Food and Drug Administration, 2014, p. 4)

Table 2: Problems with the Functioning of the General Pharmaceutical Legislation as identified by the European Commission (2020-2021)	
Problem	**Description**
Unmet Medical Need and Market Failures for Non-Orphan and Paediatric Medicines	• 7,000 rare diseases, including rare cancers in the EU, with 95% remaining untreated • Lack of breakthrough therapies in areas of unmet medical need, particularly those not covered by the orphan and paediatric regulations • Antimicrobial resistance, with current incentive models failing to provide a sustainable solution for developing therapeutic options
Unequal access to affordable medicines for patients across the EU	• New products increasingly put the sustainability of health systems at risk, with growing uncertainty as to their real-life effectiveness and related overall costs. • Innovative and promising therapies do not always reach the patient, so patients in the EU have different levels of access to medicines • Regulatory and competition barriers delay the timely entry of generics to the market and impede their uptake by health systems
The legislative framework may not be fully equipped to respond quickly to innovation	• Regulatory rules are not effectively adapted to the demands of innovation involving new technologies, such as genomic sequencing, genome editing technologies, or artificial intelligence • Fragmentation in regulatory and clinical requirements fails to capture the specificities of medicines that contain or consist of genetically modified organisms (GMOs), as well as their environmental impacts.
Inefficiency and administrative burden of regulatory procedures	• Existing regulatory procedures and internal processes often create a regulatory burden and fail to streamline timelines as intended • Regulatory agility and attractiveness fall short of global competitiveness standards in certain cases • The interplay between the General Pharmaceutical Legislation and other frameworks (such as medical devices and substances of human origin) is not fully optimised • There is untapped potential to enhance regulatory capacity through digital tools • Market authorisations lack adaptability to dynamic scientific evidence
Vulnerability of supply of medicines, quality, environmental challenges and sustainability	• Lack of adequate supply monitoring mechanisms, leading to increased supply chain vulnerabilities and shortages • Adverse environmental impact of pharmaceutical residues, waste, and antimicrobials

Table 2: Problems with the Functioning of the General Pharmaceutical Legislation as identified by the European Commission (2020-2021)

The Policy Stream: 'Snooker-tactics' Policy Entrepreneurship

Within the highly integrated policy network for market authorisation, the incremental process of attention mobilisation was accompanied by policy entrepreneurship for a transformative revision of the General Pharmaceutical Legislation. This was achieved through a three-step process of 'snooker-tactics' policy entrepreneurship, a term originally coined by this study.

In snooker, a popular billiard variant of British origin, the eponymous move – snookering – refers to a situation where a player lacking a clear line of attack attempts to gain advantage by interrupting their opponent's offense, positioning the cue ball in a spot where no direct legal shot is possible (Figure 4)[2]. The term is widely used in British English informal speech to describe situations where someone has been placed in a position where they can no longer attain what they once could, becoming trapped or obstructed.

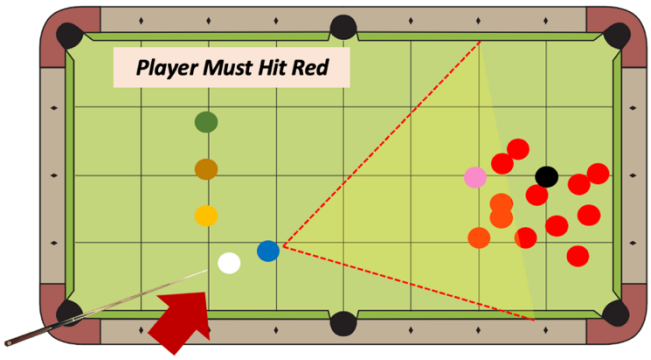


Figure 4: Visual Representation of "Snookering" in the Game of Snooker. Player must hit red with the cue ball (white) at the beginning of their turn but has no direct shot

In the context of market authorisation and innovation incentives policymaking in the EU, the establishment of the General Pharmaceutical Legislation progressively tested organisational and administrative capacity, reducing ambiguity regarding the technical feasibility of alternatives. Moreover, successive regulatory updates reinforced the prevailing policy priorities, as originally shaped by industry-oriented policy entrepreneurs, namely, the pursuit of better market outcomes through enhanced innovation incentives. Therefore, achieving a structural revision of the market authorisation regime required disrupting these long-established policymaking pathways by increasing the number and relative influence of stakeholders engaged in policy advocacy, thereby "snookering" the historically dominant, industry-oriented policy entrepreneurs.

[2] Figure 4 offers a visual representation of "snookering" within the game of snooker. The cue ball (white) has been positioned in such a way that no direct legal shot – hitting a red ball at the beginning of the turn – can be made. Therefore, Player 1, who had the previous turn, has successfully "snookered" Player 2, who now has the current turn.

The Setup: 2016 Council Conclusions

The 2016 Council conclusions were the first to contribute to the development of a counter-approach to the General Pharmaceutical Legislation. While the Council exerts a catalytic influence on policy outputs during decision-making, often fundamentally reshaping the Commission's initial proposals, its role as a policy entrepreneur during the agenda-setting stage is typically limited, due to its highly structured work programme and the frequent turnover of national political representatives (Vaznonytė, 2020; Scherpereel and Perez, 2015).

Nevertheless, given problems contain a "perceptual, interpretive element", Council conclusions can contribute to alternative conceptualisations, motivating hopeful policy entrepreneurs extend the scope of their "pet proposals" (Kingdon, 1984). With the Council attributing responsibility for market failures to the "inappropriate market behaviour of some manufacturers" (Council of the European Union, 2016), the organised representatives of disadvantaged stakeholders - namely patients' and generics associations – had firm grounds to question "the immunity enjoyed by the pharmaceutical innovation industry" within the policy network. (*Patients' Association representative*). At the same time, initiating the agenda-setting process through the EPSCO Council proved instrumental in encouraging the involvement of actors "from the field of health policy, rather than market and industrial affairs" (*Pharmaceutical Policy public affairs consultant*).

The Shot: Patients' and Generics Associations

In the immediate aftermath of the 2016 Council conclusions, patients' associations relied on their capacity as problem brokers (Knaggård, 2015) to enhance their standing within the policy network and achieve greater access to policymakers. Specifically, having emerged as unique voices of patient-driven policy feedback in the problem stream, highlighting imbalances in the EU innovation incentives system, patients' associations contributed to translating the emerging dissatisfaction into a discernible policy vision

"Access, affordability, inclusiveness and safety" provided the "four pillars of the patients' associations position", as communicated in public consultations, position papers and organised forums between 2017 and 2021 (*Patients' association representative*). In many instances, patients' representatives and health professionals pooled their resources, advocating for the revision of the "conditions to access and retain orphan medicinal product incentives" and the definition of "sufficient and excessive profitability" (AIM et al., 2020). Collective entrepreneurship (Capano and Galanti, 2021) accelerated stakeholders' efforts to position themselves within the locus of policymaking and contributed to increasing the value acceptability of the reformative positions.

The efforts of patients' associations were rewarded with success as early as 2019, when the Council, in consultation with the European Parliament, appointed Dr. Marco Greco, President of the European Patients' Forum, and Yannis Natsis, EPHA's Policy Manager for Universal Access and Affordable Medicines, as members of the EMA's Management Board (Council Decision 2019/C 195/02). Backed by Member

States and the EP, representatives of the two most outspoken EU patients' organisations were able to advance their advocacy efforts through the leading EU policy instrument on market authorisation, before subsequently turning their attention to the European Commission.

In contrast to patients' associations, the organised representatives of generics manufacturers relied less on their role as problem brokers and focused more on policy advocacy efforts directed at the EP during the 2014-2019 electoral cycle. While the revision of the General Pharmaceutical Legislation fell under the purview of the first Von der Leyen Commission (2019–2024), the preceding Juncker Commission (2014–2019), operating under an overarching "Single Market" strategy, had placed particular emphasis on supporting small and medium-sized enterprises (SMEs), including a plan to amend the SPC regime to incentivise the production of generics for third-country exports.

The Commission's proposal faced only moderate opposition from the pharmaceutical innovation industry, which "largely found the target markets of the reform unattractive" (*European Commission representative*). However, generics manufacturers, spearheaded by Medicines for Europe, successfully advocated to broaden the scope of the exemption during the decision-making stage. The European Parliament (EP), which had identified regulatory improvements for generics and biosimilars among its "Options for Improving Access to Medicines" resolution (European Parliament, 2017), supported extending the exemption for stockpiling purposes during the last six months of the SPC's validity, including in EU markets. Upon the adoption of Regulation (EU) 2019/933, Adrian van den Hoven, Director General of Medicines for Europe, commended the EP Committees "for not caving in to vested interests and foreign pressure by voting for a comprehensive SPC manufacturing waiver", calling it "the first step to stimulate competition after SPC expiry" (European Parliament and Council, 2019; Medicines for Europe, 2018).

In a legislative process separate from the ongoing deliberations on the General Pharmaceutical Legislation, generics and biosimilars manufacturers secured an invaluable stockpiling window to accelerate market entry in Member States, forged a strong alliance with the EP, and established a firmer position within the policy network. Alongside the achievements of patients' associations, this success further contributed to rebalancing policy influence and advancing 'snookering' efforts.

The Snookering: DG SANTE in the Von der Leyen Commission

The 2019-2024 EU electoral cycle marked the second-ever configuration of DG SANTE (Directorate-General for Health and Food Safety), which was rebranded in 2014 from DG SANCO (Directorate-General for Health and Consumers). The DG's leadership included a Commissioner with a particular sensitivity to rare diseases (Stella Kyriakides), personnel with extensive experience in advancing better health outcomes (John Ryan, Unit B: Public Health, Cancer, and Health Security), and outspoken critics of the IP incentives system for pharmaceuticals (Sylvain Giraud, Unit D: Medical Products and Innovation).

Crucially, unlike previous reformative efforts, DG SANTE officials determined that the challenges highlighted within the problem stream were not confined to individual aspects of the regulatory

framework (e.g., the orphan or paediatric regulations) but extended beyond them. This dynamic underscored the need for a universal revision of the General Pharmaceutical Legislation, thereby completing the shift in value acceptability and confirming H1.

Specifically, the Commission's vision, as articulated in the *Pharmaceutical Strategy for Europe* (2020) and the Roadmap/Inception Impact Assessment on the *Revision of the General Pharmaceutical Legislation* (2021), included "a tailored system of incentives that links rewards with possible obligations," such as "novel incentives that complement, replace, or adjust the market protection […] taking into account the relationship with intellectual property rights". Among the possible conditions for additional regulatory protection listed were the "development of new classes of antimicrobials" as well as "the placing on the market of the products in most/all Member States" (European Commission, 2021; 2020).

As expected, the Commission's intentions were met with resistance from the pharmaceutical innovation industry. EFPIA's official response stated categorically: "The Commission's current proposals may lead us to the worst-case scenario, limiting innovation without addressing access" (EFPIA, 2021). As elaborated by an *EU pharmaceutical industry representative* during the study's interviews: "Prices and market launches are most heavily conditional on national rules and processes. Mending pharmaceutical incentives without reforming the pricing systems responsible for delays and high price points will inevitably magnify the challenges of access and affordability instead of solving them".

Nevertheless, owing to 'snooker-tactics' policy entrepreneurship, the industry's viewpoint no longer constituted the sole or dominant policy approach, as previously marginalised stakeholders had reshaped the balance of value acceptability within the policy network (Figure 5).

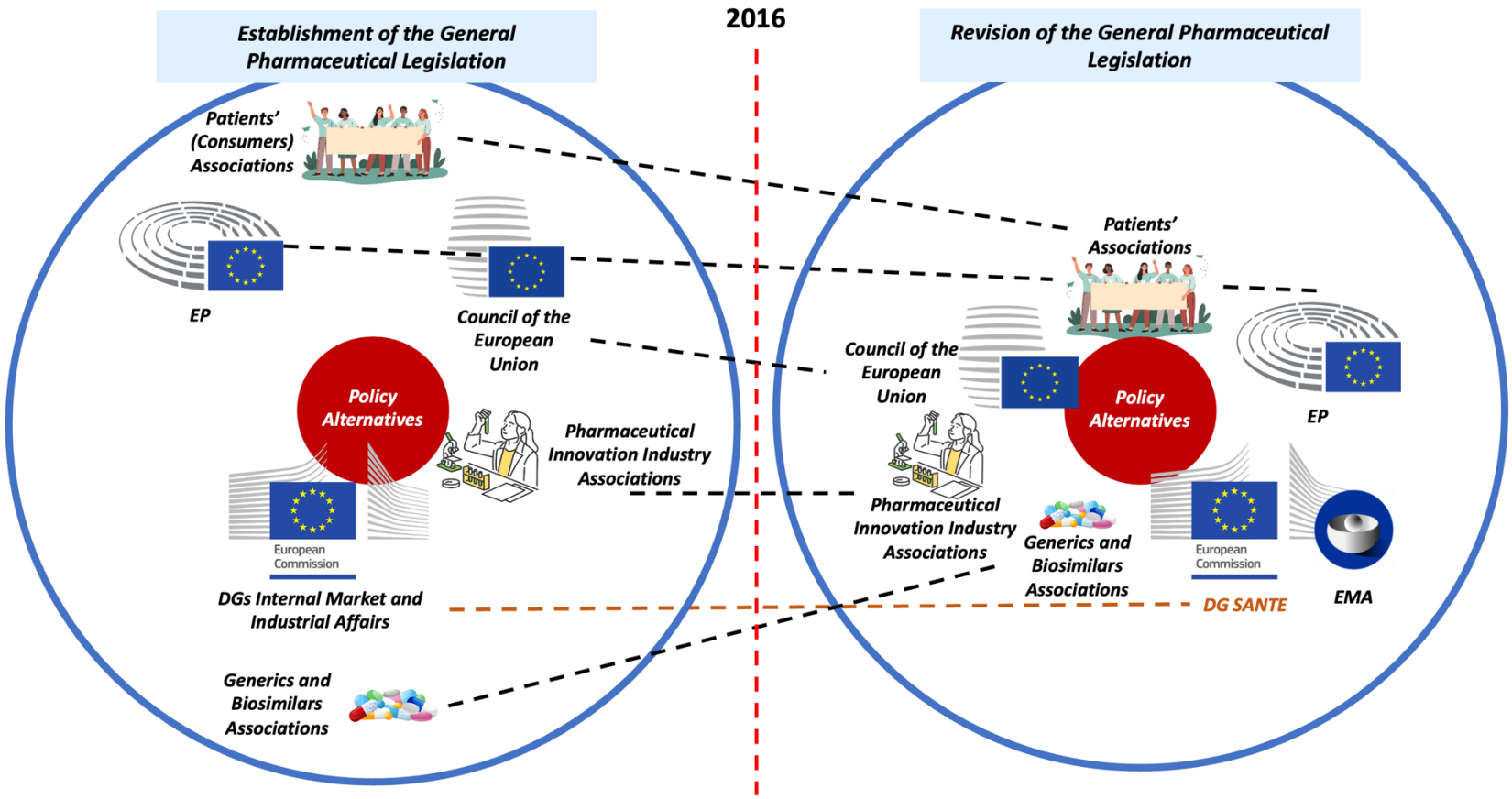


Figure 5: Evolution of the Market Authorisation and Pharmaceutical Incentives Policy Network between the Establishment and Revision of the General Pharmaceutical Legislation. Stakeholder proximity to the core indicates their influence in shaping successful policy alternatives.

The Politics Stream

Finally, to complete the process of structural legislative change, transformative policy alternatives must be coupled with sufficient political determination for reform. In the EU context, as highlighted previously, this is best examined through the narratives of the three institutions participating in the Ordinary Legislative Procedure (OLP): the European Commission, the Council, and the EP. In the case of the revision of the General Pharmaceutical Legislation, the OLP is still pending formal conclusion. However, the workings of the politics stream have indicated a convergence of institutional narratives in support of the new policy direction, towards lower, more heavily conditional innovation incentives.

Following the publication of the Roadmap/Impact Assessment (2021), as well as disruptions caused by the COVID-19 pandemic, the Commission's official proposal for the revision of the General Pharmaceutical Legislation was published in April 2023 (European Commission, 2023a; European Commission, 2023b). The proposal reflected a shift in the narrative surrounding the 'functional' perception of the EU public that the Commission typically serves; one shaped by long-term governance trends and the recent public health crisis. Specifically, whereas the Commission had previously defined 'functionality' in terms of EU-level regulatory attractiveness and expediency, this was now joined by inclusiveness and transparency, owing to the "Better Governance" era (2015–), as well as by health security and resilience, in the aftermath of the COVID-19 pandemic.

As such, the Commission proposed replacing the 8+2+1 formula with a 6-year baseline data protection period, 2 years of market exclusivity, and a combination of conditional incentives yielding up to 5 additional years of data protection (Figure 6). For the Commission, "lowering the standard duration of data protection" would "enhance competitiveness by expediting the entry of generics into the market", thereby improving access and affordability (*European Commission official)*. At the same time, regulatory attractiveness for innovation would be preserved, as manufacturers could "match or even exceed the previous 11-year data and market protection maximum through conditional incentives, provided they directed innovation toward areas of highest medical need" (*EMA official)*.

Among the notable conditional incentives were: a 2-year extension for achieving market launch in all Member States; 6-month extensions for medicines addressing unmet medical needs or supported by comparative clinical trials; and a transferable 1-year data exclusivity voucher for the development of priority antimicrobials. The market launch incentive naturally emerged as the most controversial, but it allowed the Commission to appeal to the Council's narrative *ex ante*, presenting the reform as a response to domestic market access challenges. Meanwhile, detaching unmet medical need from orphan designation aimed to "de-orphanise" innovation in rare diseases, while incentivising the development of priority antimicrobials through transferable vouchers reflected the Commission's intention to adopt a more proactive approach to current and future health threats. Last, a similar approach was adopted in the case of orphan medicines, including a dedicated incentive for addressing "High Unmet Medical Need" (HUMN) (+1 year); a new classification for orphan medicines that provide "exceptional therapeutic advancement" for diseases meeting the unmet medical need criteria.

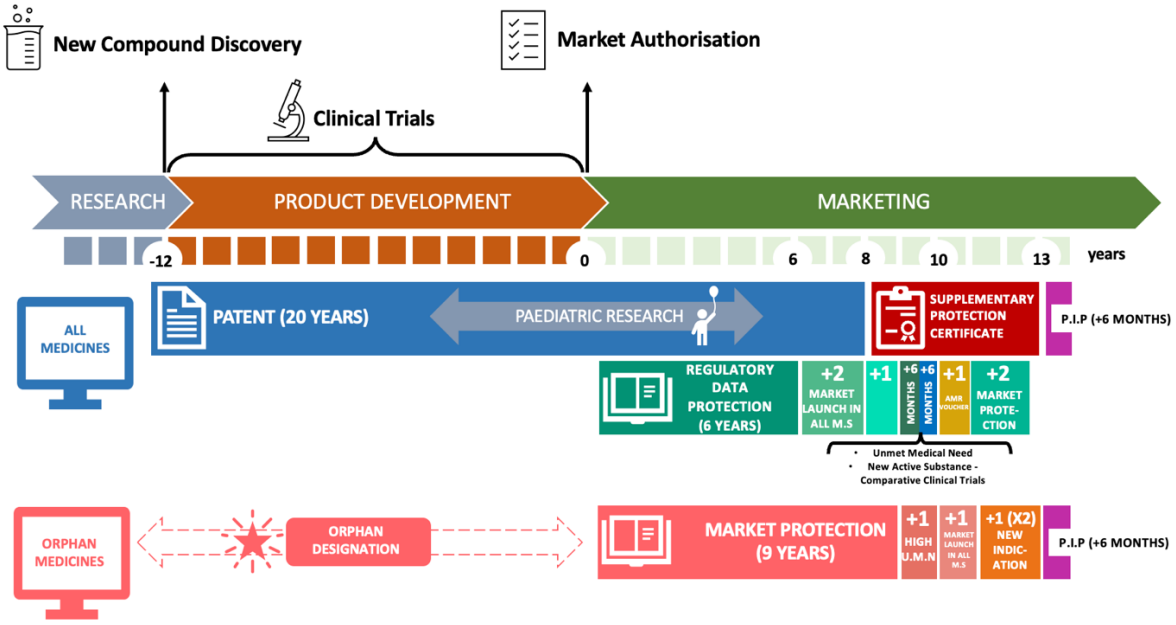


Figure 6: The IP, Market and Data Protection Framework for Innovative Medicines as provisioned by the Commission's Proposal for a Revision of the General Pharmaceutical Legislation (2023)

In June 2024, the European Parliament (EP) adopted its position on the Commission's proposal, reinforcing the proposed policy direction while seeking to align the reform with the interests of a 'popular' perception of the EU public through its amendments (European Parliament, 2024a, 2024b). To this end, emphasis was placed on the potential for continued gaming of the system, suggesting that "the 6-year baseline protection was highly unlikely to be applied in practice, given the range of conditional incentives proposed by the Commission" (*European Parliament representative)*. Additional concerns were raised about potential gridlocks, for example, in cases where manufacturers might dispute whether failures to achieve market launch within two years were due to their own responsibility.

As such, the European Parliament (EP) proposed increasing the baseline data protection period to 7.5 years, while capping the total protection at 8.5 years (Figure 7). Similarly, market protection was capped at 11.5 years. The market launch incentive was removed, and, citing the responses of patients' associations to the Commission's proposal (European Parliamentary Research Service, 2024), the EP proposed doubling the unmet medical need rewards for both centrally authorised and orphan medicines. Ultimately, the EP's amendments framed the revision of the General Pharmaceutical Legislation as "the most decisive European intervention to date to improve EU patients' access to essential innovative therapies" (European Parliament representative). As of 2025, the reform awaits its final shape, pending the Council's position.

Appendix Table 1 provides a detailed overview of the evolution of the legislative process.

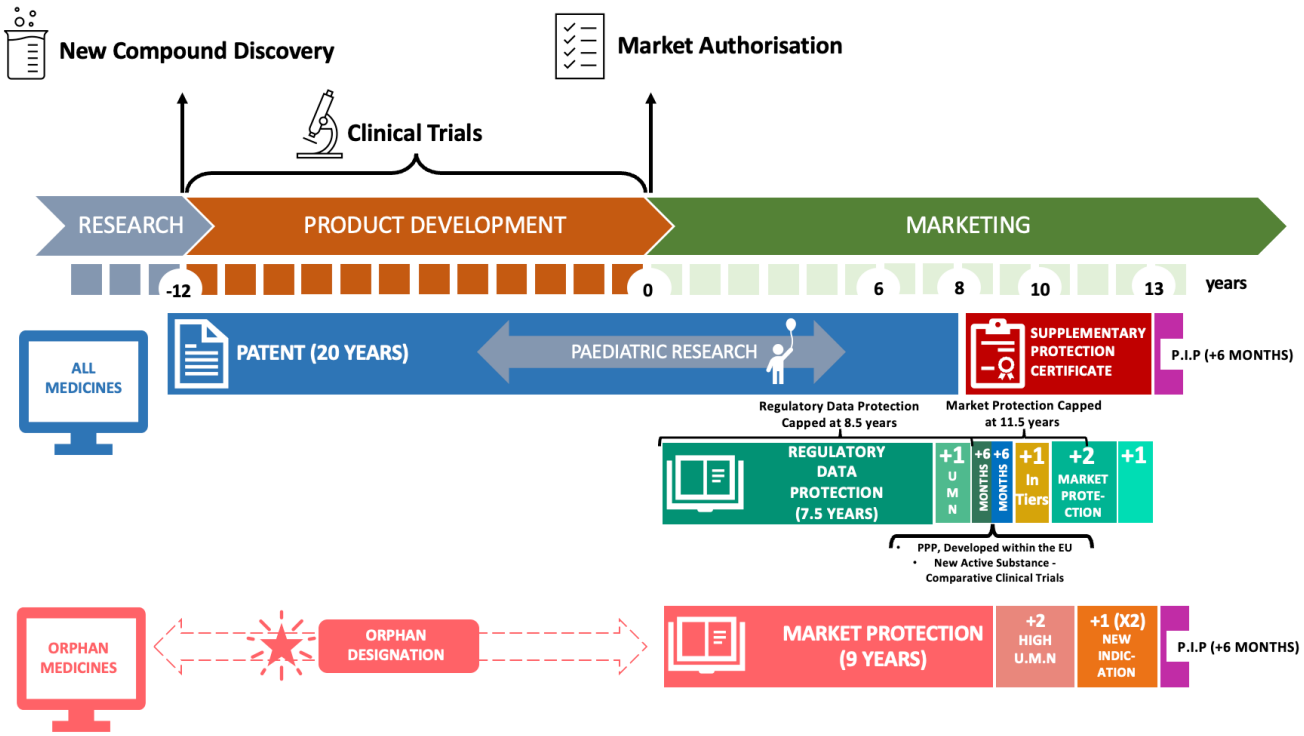


Figure 7: The IP, Market and Data Protection Framework for Innovative Medicines as provisioned by the EP's Position on the Revision of the General Pharmaceutical Legislation (2024)

The new EU HTA Framework

Overview:

"HTA is a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. The purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system." (O'Rourke et al., 2020).

Within the EU context, HTA agencies operate at the Member State level. After market authorisation has been granted by the EMA, HTA bodies are called to assess the clinical and economic added value of new health technologies. As such, HTA opinions provide important and necessary inputs for the pricing and reimbursement decisions of Member State authorities (Allen et al., 2017). Apart from medicinal products, health technologies may also include medical equipment as well as diagnostic, treatment, rehabilitation and prevention methods (Gutiérrez-Ibarluzea et al., 2017).

Historically, EU-level policy activity in HTA had been more limited compared to market authorisation and had primarily operated on a voluntary basis. Between 1993 and 2021, at the initiative of several national HTA agencies, a series of collaborative projects were launched under the European Commission's auspices and later formalised as Joint Action (JA) projects, supplemented by Member State funding (Imaz-Iglesia and Wild, 2022; Banta et al., 2009). In 2011, the European Network for Health Technology Assessment (EUnetHTA) was formalised as the "technical arm" of transnational collaboration on HTA, supplemented by an HTA network of Member State representatives (Directive 2011/24/EU). However, despite growing participation and an expanded scope, collaboration remained largely voluntary, with no institutionalised obligations for adopting joint outputs or integrating them into national policy processes.

Nevertheless, in 2018, the European Commission put forward a disruptive proposal aimed at fundamentally transforming the EU HTA landscape (European Commission, 2018a). By 2021, following the conclusion of the legislative process, a new EU HTA framework was adopted, mandating Member State participation in Joint Clinical Assessments (JCAs) for all centrally authorised medicinal products and most categories of medical devices, to be gradually implemented over time (Regulation (EU) 2021/2282).

The following sections analyse the drivers of structural reform in EU HTA after decades of minor, incremental developments, focusing on strategic policy entrepreneurship within a weakly integrated network.

The HTA Policy Network:

For more than 20 years, European HTA agencies came together on their own initiative, in growing numbers, to pursue improved health technology evaluations through collaboration. And while each collaborative project grew more ambitious than the last, the status of the EU policy network in the field of

HTA remained largely unchanged. Until the mid-2000s, most EU HTA agencies had either not yet been established or had not received their final organisational structure, including those in powerful Member States like Germany (IQWiG) and France (HAS). Meanwhile, EU institutions had not recognised any Union mandate on HTA until 2011 (Directive 2011/24/EU), while organised interest advocacy for HTA in Brussels had remained limited, especially until JA2 (2012-2015).

Therefore, the policy network for HTA at the EU level was weakly integrated and reflected the properties of the gradualist quadrant (

Figure 8). Lacking a dedicated EU-level institutional venue, the network was dispersed across multiple levels of government – extending all the way down to regional HTA authorities – with the locus of power resting in national arenas. At the same time, procedural infrastructure for EU policymaking was rudimentary and EUnetHTA's long-term continuation remained contingent on successive funding renewals. As a result, policy change consisted of phyletic transformations over protracted intervals, or simply put, an incremental evolution towards greater inter-agency collaboration.

Within this context, according to the EU-MSF (H1), achieving transformative policy change requires prolonged deliberation, focused on reconfiguring value acceptability. As such, the impending revision of the General Pharmaceutical Legislation has placed the policy network in the *emergent* quadrant, heading towards mutation after decades of paradigm stability

Within this context, the EU-MSF (H2) suggests that the success of transformative policy alternatives depends more on satisfying technical feasibility than on achieving value acceptability. Building on improvements in institutional capacity, the new EU HTA framework aims to transform the European HTA paradigm in the years ahead.

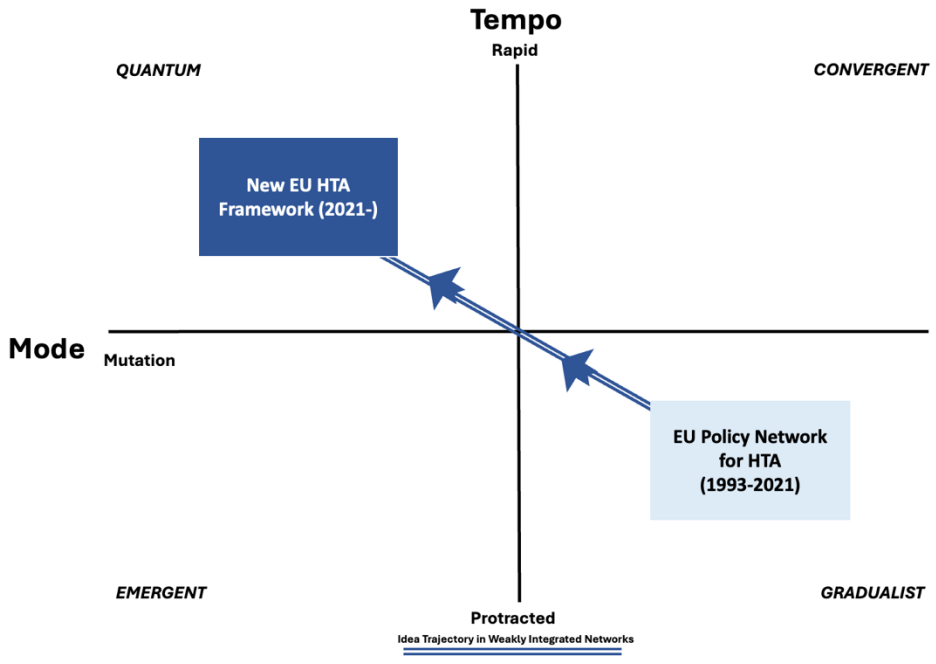


Figure 8: Evolution in the Level of Integration of the EU Policy Network for HTA

The Problem Stream:

The collaborative efforts of HTA agencies at the EU level contributed to a cumulative process of problem identification since the 1990s. Nevertheless, with Member States following different timelines in establishing dedicated instruments and defining HTA uptake mechanisms in national decision-making, "most HTA agencies lacked the institutional influence required to lobby Health Ministers and convince them to prioritise HTA issues in Brussels" (*European Commission official*). Furthermore, the absence of institutional recognition at the EU level placed significant constraints on the activation of horizontal attention mobilisation mechanisms. As a result, while EUnetHTA developed into a forum for aggregating domestic policy feedback and, to a lesser extent, domestic and EU-level indicator monitoring, it ultimately failed to mobilise the attention of policy stakeholders across the pharmaceutical policy subsystem until the mid-2010s.

Nevertheless, as in the case of market authorisation, the Eurozone crisis served as a catalyst for initiating attention mobilisation through vertical mechanisms. In light of the financial challenges facing Member States' health systems, as outlined previously, the 2014 Council Conclusions, under the Italian Presidency, highlighted the need for "more consistent approaches to HTA" as a means to enable "evidence-based, sustainable, and equitable choices in healthcare and health technologies for the benefit of patients" (Council of the European Union, 2014).

EPSCO's calls redirected EU institutional attention toward pricing and reimbursement and, by extension, HTA. In this context, the European Commission and interest associations became actively involved, bringing to light en masse the challenges facing HTA in the EU policy arena, most of which had already been prominently featured in EUnetHTA outputs over the years.

Specifically, the process of horizontal attention mobilisation was structured around the 2016 Roadmap/Inception Impact Assessment for the "Strengthening of EU Cooperation on Health Technology Assessment (HTA)", communicated by the European Commission (European Commission, 2016). The initiative had a distinctly exploratory scope, aiming to summarise the state of HTA in the EU, formally recognise long-standing challenges, and survey stakeholder preferences for legislative or non-legislative policy outputs. The assessment identified five core problems which permeated the EU's experience with HTA.

First, the European Commission focused on the *adverse effects of duplication*, i.e., the repetition of HTA assessments for the same medicinal products across Member States. "HTAs are multidimensional, and many elements, such as ethical or legal considerations are reasonably controversial given the large

discrepancies in the political and health systems of Member States" (*Pharmaceutical Industry representative*). To enhance the transferability of assessments and encourage transactional gains, EUnetHTA stakeholders developed the HTA Core Model as early as 2006, a framework that identifies the key domains of HTA, drawing on both European and international experience (EUnetHTA, 2009). The HTA Core Model distinguishes between the technical and clinical elements of health technology evaluations and their economic, social, legal, and ethical aspects. The former are the focus of a narrower version of HTA, known as the Rapid Relative Effectiveness Assessment (REA) (EUnetHTA, 2012), which, "in theory, should be where most of us [HTA Agencies] can agree, given that we evaluate the same technologies within a Single Market setting" (*National HTA Agency representative*).

Nevertheless, despite the increasing use of the HTA Core Model as a foundation for joint assessments, national-level uptake remained consistently low; below 20% and often involving significant adaptations (EUnetHTA, 2018). At the same time, each individual evaluation at the national level was estimated to cost agencies between €30,000 and €100,000, and the industry between €100,000 and €200,000 (Ecorys, 2013).

Furthermore, the Roadmap/Inception Impact Assessment highlighted significant variation among national HTA settings in terms of the *duration and number of required processes*, *the scope of assessments* (i.e., which health technologies are included), and *the number of HTAs conducted annually*. Special emphasis was placed on *medical devices and in vitro diagnostics*, an emerging industry that remained subject to minimal HTA coverage in most Member States (European Commission, 2018b).

At the same time, beyond variation in processes, substantial differences were also identified in the *methodologies* employed by EU HTA agencies during both Full HTAs and REAs. "The variety in data requirements for the industry and the divergent outcomes of evaluations" often delayed, restricted (through higher prices), or altogether prevented patients' access to new health technologies (European Commission, 2016). For several Member States, preserving methodological divergence was viewed as a means to prevent a "race to the bottom in terms of evaluation standards" (*National HTA Agency representative*). Nevertheless, the relative importance attributed to different HTA components, and the selection of supplementary material were repeatedly cited as barriers to market access across Member States (Beck et al., 2019).

The Policy Stream

In the case of HTA, the process of attention mobilisation became inextricably linked to the workings of the policy stream, as the prospect of structural reform emerged through 'recoil-tactics' policy entrepreneurship", exercised by the European Commission between 2016 and 2018.

When a force is applied to a system, such as an explosion inside the chamber of a gun, internal elements are propelled and stretched as far as the exerted force pushes them. However, following the action comes a reaction, pulling the system back toward equilibrium; though now at a different point, shaped by the

initial force. This process, known as recoil, resembles the Commission's approach to its ambitious and disruptive proposal for a new EU HTA framework in 2018 (European Commission, 2018a).

Within the modern EU political system, particularly since the launch of the Better Regulation Agenda by the Juncker Commission in 2015, the institutionalisation of public consultations and Roadmaps/Inception Impact Assessments has introduced new dynamics to the agenda-setting process (OECD, 2022; Bunea and Ibenskas, 2017; European Commission, 2015). Specifically, while the Commission is obligated to engage in preliminary impact evaluations, comparing the likely effects of policy options and inviting stakeholder input in the process, it retains considerable discretion over both the content and scope of these activities; a flexibility that offers strategic advantage in policy entrepreneurship. As such, the Commission may communicate a clear policy orientation and gauge its acceptance among affected stakeholders, as in the case of the revision of the General Pharmaceutical Legislation. However, the Commission may also adopt a more tentative approach, aimed at identifying challenges that may or may not require an EU-level response, informing interested stakeholders of potential policy options and their associated costs, and systematically assessing the balance of policy preferences.

In the case of the new EU HTA framework, the Commission followed the latter course of action. As highlighted in the problem stream, the 2016 Roadmap/Inception Impact Assessment on HTA adopted an exploratory scope, listing all conceivable policy options for the future of EU HTA cooperation – from maintaining the status-quo to establishing a comprehensive, centralised system encompassing both REAs and Full HTAs (Table 3) (European Commission, 2016).

Table 3: Policy Options for HTA as identified in the European Commission's Roadmap/Inception Impact Assessment, 2016							
Policy Option	**Description**	**Financing**	**Intervention**	**Common Tools**	**REAs**	**Full HTAs**	**Early Dialogues**
1: **Status Quo**	HTA is regulated and organised at the national/regional level. Following the expiry of the third Joint Action in 2020, and assuming no further action is taken (baseline scenario), there will be no EU cooperation scheme in place afterward.	Current model, until 2020: Jointly funded by the EU Health Programme and Member States	Non-Legislative	Voluntary	Voluntary	Voluntary	Voluntary
2: **Long-term voluntary cooperation**	Continuation of the current cooperation model, but on a longer-term basis.	Long-term financing mechanism, most likely through the EU Public Health Programme	Non-Legislative	Voluntary	Voluntary	Voluntary	Voluntary
3: **Cooperation on collection, sharing and use of common tools and data**	Introduction of a legal framework for HTA cooperation, enabling the efforts by national bodies to be compatible, shared and used. Production of joint REA reports on a voluntary basis. Established processes for the use of common tools and early dialogues.	Financing model with EU and Member State contributions as well as industry fees	Legislative	Mandatory	Voluntary	Voluntary	Mandatory
4: **Cooperation on the production and uptake of joint REA reports**	Member States jointly produce REAs, available to all through a shared repository, with measures for the uptake of the joint work at national level. The assessment of non-clinical domains would remain under the responsibility of Member States.	Permanent/continuous support from the EU, including for a supporting organisational structure. Additionally, Member State contributions and industry fees	Legislative	Mandatory	Mandatory	Voluntary	Mandatory
5: **Cooperation on the production and uptake of joint Full HTA reports**	Joint production of Full HTA reports	Permanent/continuous support from the EU, Member State contributions and industry fees. Costs likely higher than option 4	Legislative	Mandatory	Mandatory	Mandatory	Mandatory

Table 3: Policy Options for HTA as identified in the European Commission's Roadmap/Inception Impact Assessment, 2016

Moreover, the Commission opted to pair the Roadmap/Inception Impact Assessment with a structured public consultation. Policy stakeholders interested in the future of HTA policymaking in the EU submitted their contributions via a dedicated questionnaire, providing their views on the relative importance of the identified problems and the attractiveness of the proposed policy options[3] (European Commission, 2017). The Commission's approach to the public consultation prompted the simultaneous communication of policy preferences by participants in the weakly integrated policy network, both directly and indirectly, within a structured format.

A comparative breakdown of public consultation responses on the usefulness of European HTA outputs revealed high levels of support for joint tools, guidelines, early dialogues, and REAs from both patients' associations and the pharmaceutical innovation industry; the sector's leading interest groups (Figure 9). Notably, patients' preferences extended to joint Full HTAs, whereas the pharmaceutical industry maintained a more reserved stance. Meanwhile, representatives of national HTA agencies, health ministries, and other relevant public organisations also endorsed the usefulness of most joint outputs, but echoed the pharmaceutical industry's reservations regarding Full HTAs. By contrast, representatives of the medical devices industry – traditionally less subject to HTA – expressed significantly lower levels of support for all joint outputs, including both REAs and Full HTAs, than any other stakeholder group.

[3] The public consultation on HTA amassed 249 responses including 63 from citizens, 97 from pharmaceutical industry representatives, 27 from public administration representatives, 24 from patients and consumers representatives, 16 from healthcare providers, 8 from academics, 5 from payers and 9 from participants with other relevant roles (European Commission, 2017).

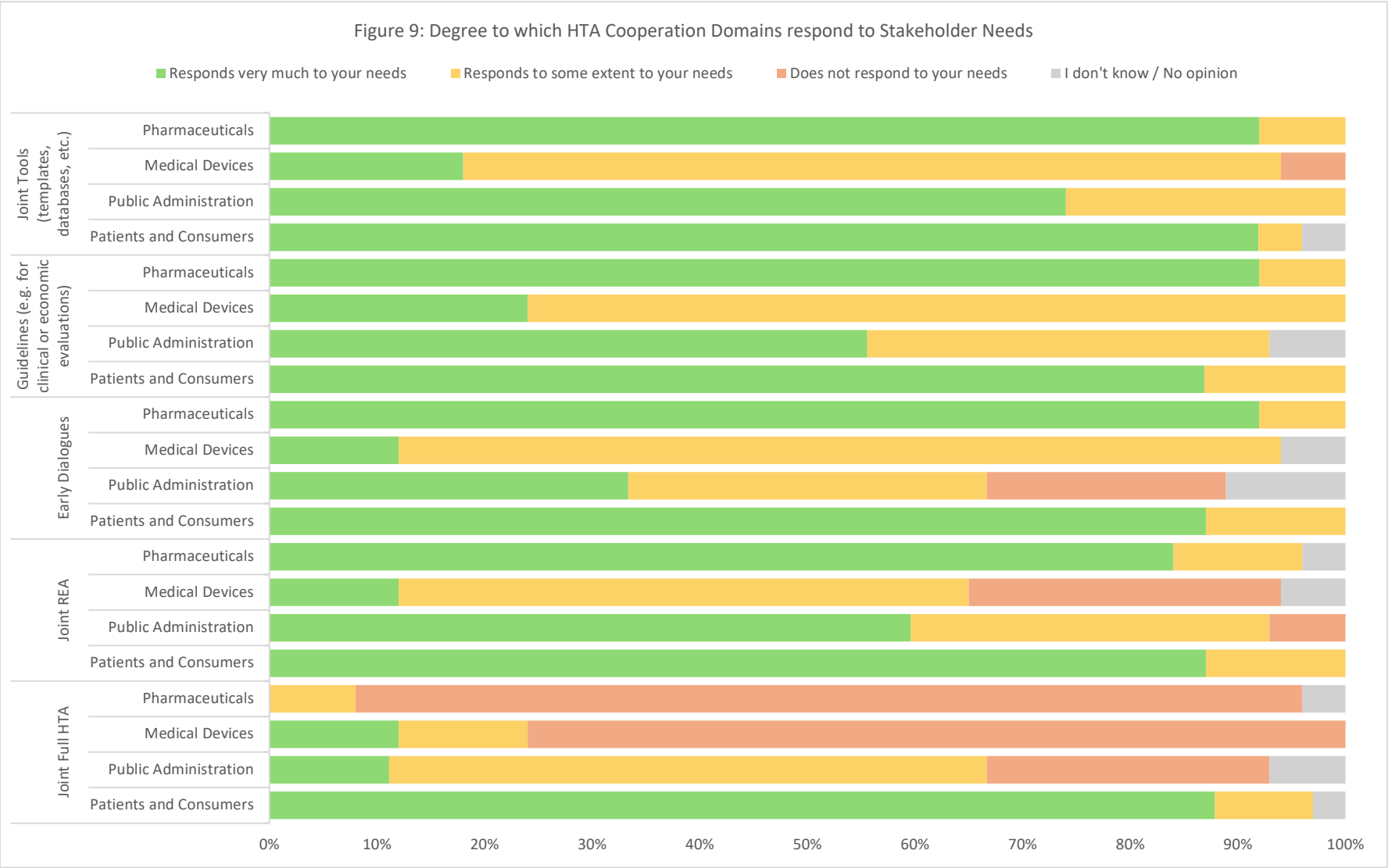


Figure 9: Degree to which HTA Cooperation Domains respond to Stakeholder Needs

Crucially, contributions to the dialogue extended beyond the public consultation inputs. Table 4 summarises the policy preferences of all participants in the EU-level policy network for HTA vis-à-vis joint assessments following the 2016 Roadmap/Inception Impact Assessment.

The European Parliament joined patients' associations, the pharmaceutical innovation industry, and HTA agencies in advocating for a system of joint REAs with mandatory uptake (European Parliament, 2017). For most stakeholders, mandatory participation in joint outputs was of secondary importance, as they recognised the limited capacity and resources of several European HTA agencies. As stressed by HIQA (Ireland): *"we are too small of an organisation"* (HIQA, 2017).

However, the mandatory uptake of REAs was viewed as necessary to justify the investment of resources into joint work. Patients and the pharmaceutical innovation industry, in particular, favoured "single-dossier REAs" to "streamline the pricing and reimbursement process" and "enhance safety and transparency across Member States", respectively (*Pharmaceutical Industry and Patients' Association representatives*). Nevertheless, national HTA agencies were more divided on the issue. More resourceful agencies, such as HAS (France), expressed concerns that mandatory uptake could result in "the adoption of the lowest common denominator in terms of quality of work" (HAS, 2017). As such, they favoured a system of mandatory uptake, albeit with room for national-level adaptations.

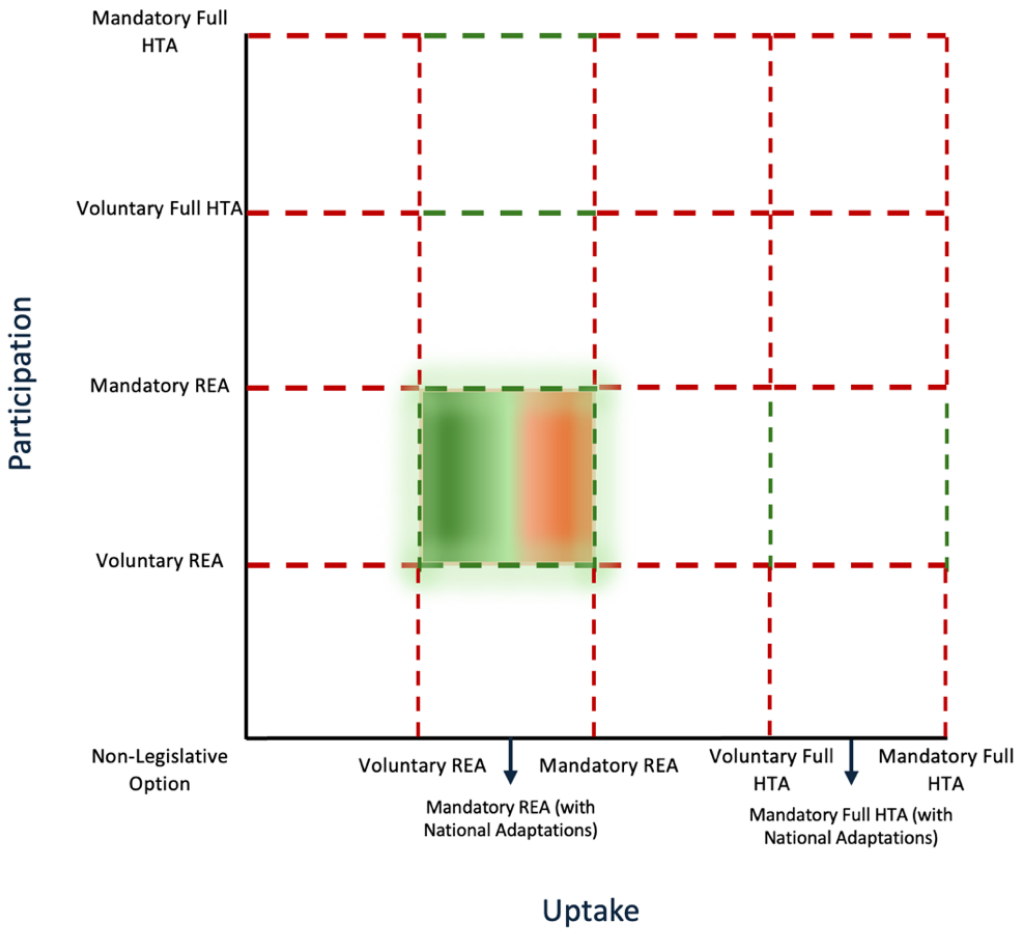
Finally, this latter approach proved most acceptable to the Council, which, excluding the medical devices industry, expressed the strongest resistance to a structural transformation of the HTA regime in the EU. As summarised by a *Coreper representative* during the interviews, *"*Member State positions on HTA were dependent on the trade-off between financial and transactional gains on the one hand and proportionality and subsidiarity concerns on the other*"*. For countries where the former outweighed the latter – usually due to less robust pricing and reimbursement systems – binding harmonisation was deemed favourable, and vice versa. Nevertheless, even among supporters, there were explicit calls to guarantee the possibility for "national adaptations of joint work" (Finnish Ministry of Health, 2017).

Table 4: Policy Network Preferences for the Framework of HTA Cooperation beyond 2020										
Actor/Institution ID	**Policy Alternatives**									
	Non-Legislative Continuation of HTA Cooperation	Voluntary Participation in REA	Voluntary Uptake of REA	Mandatory Participation in REA	Mandatory Uptake of REA with National Adaptations	Mandatory Uptake of REA	Voluntary Participation in Full HTA	Mandatory Participation in Full HTA	Mandatory Uptake of Full HTA with National Adaptations	Mandatory Uptake of Full HTA
HTA Agencies	**Low Preference**	**High Preference**	**Moderate Preference**	**Low Preference**	**High Preference**	**Moderate Preference**	**Moderate Preference**	**Low Preference**	**Low Preference**	**Low Preference**
Pharmaceuticals	**Low Preference**	**High Preference**	**Low Preference**	**Low Preference**	**Moderate Preference**	**High Preference**	**Low Preference**	**Low Preference**	**Low Preference**	**Low Preference**
Medical Devices	**High Preference**	**Low Preference**	**Low Preference**	**Low Preference**	**Low Preference**	**Low Preference**	**Low Preference**	**Low Preference**	**Low Preference**	**Low Preference**
Patients	**Low Preference**	**Low Preference**	**Low Preference**	**High Preference**	**Moderate Preference**	**High Preference**	**Moderate Preference**	**High Preference**	**High Preference**	**High Preference**
Council	**Moderate Preference**	**High Preference**	**Moderate Preference**	**Low Preference**	**Moderate Preference**	**Low Preference**	**Low Preference**	**Low Preference**	**Low Preference**	**Low Preference**
European Parliament	**Low Preference**	**Moderate Preference**	**Moderate Preference**	**High Preference**	**High Preference**	**High Preference**	**Low Preference**	**Low Preference**	**Low Preference**	**Low Preference**

Table 4: Policy Network Preferences for the Framework of HTA Cooperation beyond 2020

Therefore, by 2017 – without yet having submitted an official proposal for reform – the Commission had successfully leveraged the public consultation to pre-emptively aggregate policy preferences within a weakly integrated network lacking systematic interaction among affected stakeholders. Specifically, by mass-communicating problems that had accumulated within EUnetHTA forums over decades and prompting policy actors to deliberate on all conceivable policy options, the Commission was able to chart a range of "feasible" policy alternatives.

Confirming H2, no policy option exhibited consensus-level value acceptability; however, stakeholders did converge in their assessments of technical feasibility, which in turn primarily shaped their policy preferences (for example, the pharmaceutical industry's support for mandatory uptake in joint REAs, but not in Full HTAs). As such, the Commission could confidently deem some degree of institutionalised cooperation on HTA, centred around joint REAs, as technically feasible, with uptake emerging as the most controversial dimension when shifting from more voluntary to more mandatory models. Therefore, it could propose any policy option within this range of feasibility, knowing that even after likely pushback, the resulting "recoil" would still constitute substantial policy change, breaking with decades of incrementalism.



The Politics Stream

Completing the deployment of 'recoil-tactics' policy entrepreneurship, the Commission "stretched" the politics stream – just as it had previously done with the problem and policy streams. On 31 January 2018, a year after the conclusion of the public consultation, the European Commission submitted a *Proposal for a Regulation of the European Parliament and of the Council on Health Technology Assessment and Amending Directive 2011/24/EU* (European Commission, 2018a). The Commission's proposal stood in full alignment with the 'functional' perception of the EU public that it typically serves.

First, and most radically, the Commission proposed a transition to joint clinical assessments (REAs) for all medicinal products undergoing the central market authorisation procedure, as well as for high-risk medical devices and in vitro diagnostics. The Commission's 'functional' narrative echoed the policy feedback of patients' associations, the pharmaceutical industry, and HTA decision-makers, promoting EU-level consistency and transparency as substantial improvements to the evidence base for pricing and reimbursement processes. In line with this, the proposal also stipulated that the methodological framework for conducting JCAs would be established by the Commission and that assessments would be published at the time of, or shortly after, the EMA's market authorisation decisions.

Beyond JCAs, the Commission's proposal also provided for the conduct of Joint Scientific Consultations (JSCs), annual horizon scanning for emerging health technologies, and a framework for voluntary cooperation on non-clinical assessments and non-high-risk medical devices. The executive responsibilities for JCAs, JSCs, and horizon scanning would be delegated to a new EU-level instrument, the 'Coordination Group', made up of national HTA agency representatives appointed by Member States (European Commission, 2018a).

Responding to the Commission's proposal, the European Parliament showed strong support for the outlined policy direction, while introducing amendments to frame the new EU HTA framework in line with the 'popular' perception of the EU public it typically serves. Most notably, the EP complemented Article 114, originally selected by the Commission as the legal basis for the reform, with Article 168(4) of the TFEU, framing the HTA Regulation not only in relation to internal market improvements but also to public health protection. As such, the EP advocated for even more expansive coverage of JCAs and emphasised unmet medical need considerations in the selection of medical devices and in vitro diagnostics, the evaluation of JSC requests, and the voluntary aspects of Member State cooperation. Moreover, the EP enhanced the legislative provisions on transparency and accountability – including conflict of interest measures – to promote public scrutiny of JCAs and JSCs, and to frame the reform as an improvement in decision-making pluralism and fairness.

Last, the Council converged on a policy position by 2021, tailoring the proposal to the interests of a 'ruling' perception of the EU public. For the more sceptical Member States, the proposal's "very far-reaching measures" were seen as a threat to the "tried and tested procedure for testing medicinal products"

(German Bundestag, 2018). As such, they conflicted with the narrative of empowering national health systems to make safe and efficient decisions by reducing regulatory dissonances within the internal market.

Consequently, the Council's amendments to Regulation (EU) 2021/2282 focused on considerations of necessity and on reinforcing Member States' ownership of domestic HTA outcomes. First, the mandate for developing the JCA and JSC methodologies was transferred from the Commission to the Member States. Second, an incremental implementation timeline was introduced, beginning with cancer medicines and high-risk medical devices, and expanding to all medicinal products by 2030. The Council's insistence on an incremental approach reaffirmed the importance of technical feasibility, as proposed in H1. As noted by a *European Commission representative*, "at the current stage, we are not looking at anything more than 10 JCAs for the first year." From a narrative standpoint, the incremental implementation approach also enabled the prioritisation of the most expensive medical technologies – those most likely to be unattainable for patients in several Member States – while allowing the Coordination Group to adjust and expand based on experience.

Last, and most notably, the obligations for mandatory uptake were reduced. The Council successfully advocated for Member States to retain the ability to supplement or revisit JCA conclusions, while requiring them to give due consideration to the published JCA reports, annex them to domestic assessments, and refrain from requesting clinical data or other evidence already submitted at the EU level. Upon the conclusion of the decision-making process, the Council's more reserved political determination effectively constrained the initial ambition of the reform. Nevertheless, despite the expected pushback, the legislative process still delivered the most significant structural reform of HTA to date, thereby crowning the Commission's 'recoil-tactics' policy entrepreneurship with success (Figure 10).

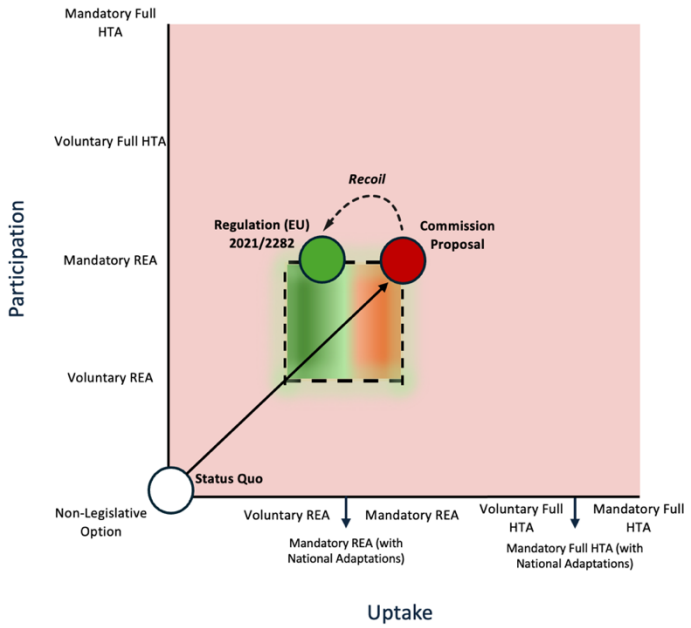


Figure 10: 'Recoil-tactics' Policy Entrepreneurship in the case of the new EU HTA Framework (Regulation (EU) 2021/2282)

Discussion - Conclusions

Ultimately, why do EU-level policies change? And how does policy network integration shape the nature of favourable policy alternatives and the success of policy entrepreneurship strategies? The analysis of two recent structural reforms in EU pharmaceutical policy yields conclusions that advance EU policy process research, the literature on the MSF and policy entrepreneurship, and the broader understanding of policymaking in multi-level governance contexts, both in times of normalcy and crisis.

Employing a process-tracing approach, guided by the EU-MSF (Karokis-Mavrikos, 2025), the analysis tested and confirmed two hypotheses linking the level of policy network integration to the defining features of transformative policy alternatives. As demonstrated in the case of the revision of the General Pharmaceutical Legislation, policy deliberation in highly integrated EU policy networks is less concerned with technical feasibility, as high administrative capacity reduces ambiguity around organisational and procedural capabilities. However, systematic stakeholder interaction, high barriers to entry, and the EU's tendency towards regulatory fine-tuning favour the establishment of policy monopolies (Baumgartner & Jones, 1993) – in this case, composed of industry-oriented policy entrepreneurs within both the institutional arena (Commission DGs on the Single Market and Industrial Affairs) and the interest arena (EFPIA).

Consequently, disruptive policy entrepreneurship must reconfigure value acceptability by challenging the policy monopoly. 'Snooker-tactics' policy entrepreneurship, as introduced in this study, captures the process of disrupting established policy pathways by bringing new or "louder" voices into the core of policy advocacy. This process likely involves: (a) a stimulus for an alternative problem definition – such as the Eurozone crisis, a focusing event, linking pharmaceutical incentives to the access and affordability struggles of Member States; (b) a growth in resources and influence among previously marginalised policy entrepreneurs – such as patients' and generics associations; and (c) a shift in policy venues – in this case, towards DG SANTE. Nevertheless, given the high level of network integration, this process is likely to remain internal to the policy subsystem. As such, disruptive policy entrepreneurs, who are already members of the policy network, may rely on problem brokering (Knaggård, 2015), collective entrepreneurship (Capano & Galanti, 2021), membership in key policy instruments (e.g. the EMA), or strategic alliances with institutional actors forged over adjacent reforms to enhance their relative standing.

In contrast, in weakly integrated EU policy networks, value acceptability becomes secondary to technical feasibility for the successful adoption of transformative policy alternatives. The case of the new EU HTA framework illustrates how, even in policy domains characterised by fluid participation, low barriers to entry, and a legacy of incrementalism, policy entrepreneurship that effectively leverages technical feasibility can drive structural reform. As weakly integrated networks tend to be more dispersed across levels of government, policy entrepreneurs within EU institutions may be best positioned to shape policy outputs. The analysis demonstrated that, while stakeholders representing national HTA agencies had made commendable progress in their collaborative efforts since the 1990s, these initiatives remained largely confined within the EUnetHTA silo. By contrast, in the aftermath of the Eurozone crisis, policy

entrepreneurs in DG SANTE were able to capitalise on the problem-driven window of opportunity and structure policy deliberation across the weakly integrated network.

Integral to the Commission's deployment of 'recoil-tactics' policy entrepreneurship – as introduced in this study – was the strategic use of the Roadmap/Inception Impact Assessment and the associated public consultation. By adopting an exploratory scope for the EU HTA Roadmap and inviting structured feedback, the Commission was uniquely able to chart policy preferences across the weakly integrated policy network and gain an advantage in managing ambiguity. Having established a range of technically feasible alternatives, the Commission was subsequently able to proceed with an ambitious proposal and ultimately drive structural reform, despite the largely expected pushback during decision-making. As such, the study's conclusions offer valuable insights into the impact of the public consultation regime on the EU agenda-setting process and, potentially, on similar forums for preference aggregation in multi-level governance settings, such as the G7 or the World Trade Organization (WTO).

In conclusion, the EU-MSF approach adopted in this study underscores the need for systematic policy process research at the EU level. The key findings advance the broader MSF research agenda on policy networks (Zahariadis, 2003) and the policy entrepreneurship literature (Petridou & Mintrom, 2021), while contributing to the development of the EU-MSF into a research programme grounded in testable hypotheses (Sabatier, 1998). Compared to existing approaches, the EU-MSF excels at navigating the EU's multi-level governance architecture and isolating the impact of key drivers, including crises, on policy outcomes. Ultimately, the same focusing event—the Eurozone crisis—triggered two vastly different policy trajectories towards structural reform, owing to variations in policy network integration and policy entrepreneurship. At the same time, the COVID-19 pandemic popularised narratives of resilience and health security that proved crucial to policy adoption. Therefore, beyond driving emergency responses, crises exert an asynchronous impact on multi-level governance networks – an impact that is best understood by effectively examining the politics of normalcy.

As of 2025, EU pharmaceutical policy is entering a new era, marked by paradigmatic shifts in both pharmaceutical incentives – towards lower protection and greater conditionality based on unmet medical need – and HTA – towards a system of joint JCAs. Both reforms are likely to reconfigure policy network integration, thereby demanding new strategic action from future policy entrepreneurs.

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Regulation (EU) 2021/2282

Roadmap/Impact Assessment (2021)

Appendix

Appendix Table 1: Evolution of the Legislative Provisions for the Revision of the General Pharmaceutical Legislation			
Legislative Provisions	**General Pharmaceutical Legislation**	**European Commission Proposal (2023)**	**European Parliament Position (2024)**
Standard Regulatory Data Protection	**8 Years**	**6 Years**	**7.5**
Additional Regulatory Data Protection	***- Non-Cumulative with Baseline Protection -*** **+ 1 Year** for a new therapeutic indication for a well-established substance **+1 Year** for a change in classification of a medicinal product on the basis of significant pre-clinical tests or clinical trials	***- Cumulative with Baseline Protection-*** **+ 2 Years** if market launch in all M.S is achieved within 2 years of marketing authorisation - Or if launch is achieved within 3 years of marketing authorisation for SMEs with less than 5 centralised marketing authorisations or non-profit entities **+ 6 Months** if the medicine addresses unmet medical need **+ 6 Months** for a new active substance, where comparative clinical trials are conducted **+ 1 Year** for a new therapeutic indication approved during the period of data protection and if supported by data that shows a significant clinical benefit over existing therapies ***- Non-Cumulative with the 6 Year Baseline -*** **4-Year** period of data protection for new indications of repurposed medicinal products provided that the indication is of significant clinical benefit and that the medicine has not previously benefitted from data protection, or 25 years have passed since the granting of the initial marketing authorisation	***- Cumulative with Baseline Protection but capped at a Maximum of 8.5 Years -*** **+ 1 Years** for products addressing unmet medical need **+ 6 Months** for a new active substance, where comparative clinical trials are conducted + **6 Months** for products developed mostly within the EU, and at least via one public-private partnership with EU research entities
Standard Market Exclusivity Protection	**Data Exclusivity + 2 Years**	**Data Exclusivity + 2 Years**	**Data Exclusivity + 2 Years**

Additional Market Exclusivity Protection	**+1 Year** market protection for a new therapeutic indication which brings significant benefit in comparison with existing therapies	---	***- Cumulative with Standard Market Exclusivity but capped at a Maximum 11.5 Years of Total Market Protection -*** **+ 1 Year** for a new therapeutic indication approved during the period of data protection and if supported by data that shows a significant clinical benefit over existing therapies
Additional IP Protection for Paediatric Medicines	**+6 Months** extension to the SPC for completing a Paediatric Investigation Plan (PIP)	---	--
Standard Market Exclusivity Protection for Orphan Medicines	**10 Years**	**9 Years**	**9 Years**
Additional Market Exclusivity Protection for Orphan Medicines	**+ 2 Years** for an orphan-designated condition when the results of specific studies are reflected in the summary of product characteristics (SmPC) addressing the paediatric population and completed in accordance with a fully compliant paediatric investigation plan (PIP) ***- Still applies, although unlikely -*** **+1 Year** market protection for a new therapeutic indication which brings significant benefit in comparison with existing therapies	+ **1 Year** for addressing High Unmet Medical Need **+ 1 Years** if market launch in all M.S is achieved within 2 years of marketing authorisation - Or if launch is achieved within 3 years of marketing authorisation for SMEs with less than 5 centralised marketing authorisations or non-profit entities **+ 1 Year** for new orphan indication. This can apply to a maximum of two new orphan indications and grant a maximum of **2 additional years** of market exclusivity ***- Special Case -*** **5 Years** for well-established Orphan Medicinal Products, i.e. when an active ingredient has been used for more than ten years and its efficacy and safety are established. Market Exclusivity can be obtained using bibliographical data and not primary clinical results	**+ 2 Years** for addressing High Unmet Medical Need **+ 1 Year** for new orphan indication. This can apply to a maximum of two new orphan indications and grant a maximum of **2 additional years** of market exclusivity ***- Special Case -*** **4 Years** for well-established Orphan Medicinal Products, i.e. when an active ingredient has been used for more than ten years and its efficacy and safety are established. Market Exclusivity can be obtained using bibliographical data and not primary clinical results
EMA	Assessment Time: 210 Days	Assessment Time: 180 Days	Assessment Time: 180 Days

	Commission Authorisation Time: 67 Days	Commission Authorisation Time: 46 Days Accelerated Procedure: 150 Days Total Temporary emergency marketing authorisation for public health emergencies Data review in phases process for promising medicines that offer exceptional therapeutic advancement Digitisation	Commission Authorisation Time: 46 Days Accelerated Procedure: 150 Days Total Temporary emergency marketing authorisation for public health emergencies Data review in phases process for promising medicines that offer exceptional therapeutic advancement Digitisation
AMR	---	Transferrable Exclusivity Voucher for the development of Priority Antimicrobials - **+1 Year** of Data Exclusivity for a single centrally authorised medicinal product within its first four years of regulatory data protection.	Transferrable Exclusivity Voucher for the development of Priority Antimicrobials -Additional Data Exclusivity for a single centrally authorised medicinal product within its first four years of regulatory data protection. - **+1 Year** for authorised products classified as "**Critical**" according to the WHO Pathogens List - **+9 Months** for authorised products classified as "**High**" according to the WHO Pathogens List - **+6 Months** for authorised products classified as "**Medium**" according to the WHO Pathogens List Milestone payments managed by the Commission for priority anti-microbials' development, market authorisation applications and stewardship Establishment of a subscription model for the joint procurement of antimicrobials (connected to delinking funding from volume sales, commitment to continuous supply in pre-agreed quantities and submission of a global access plan to supply third countries)

Appendix Table 1: Evolution of the Legislative Provisions for the Revision of the General Pharmaceutical Legislation

Appendix Table 2: Comparative Overview of the Commission's Proposal, the EP's Amendments and the Final Version of Regulation (EU) 2021/2282			
Legislative Provisions	**European Commission**	**European Parliament**	**Council of the European Union (Regulation Final Draft)**
Governance Mechanism	**Member State Coordination Group:** Executive and strategic responsibilities, including an Annual Work Programme and Annual Report Comprised of national authorities and bodies responsible for health technology assessment, appointed by Member States on an ad-hoc or permanent basis Decisions by consensus, or, where necessary, by simple majority Dedicated sub-groups for joint clinical assessments, joint scientific consultations, identification of emerging health technologies, voluntary cooperation, preparation of the annual work programmes and annual reports, and updates of the common rules and working documents **Support Framework:** Commission: Responsibility to host, oversee and co-chair the meetings of the Coordination Group, provide secretariat, administrative, scientific and IT support, and facilitate cooperation between the Coordination Group, the EMA and relevant Union bodies on medical devices Stakeholder Network: open call and selection process, informational exchanges with the Coordination Group, may nominate clinical experts and patients to attend meetings of the Coordination Group as observers	**Member State Coordination Group:** Executive and strategic responsibilities, including an Annual Work Programme and Annual Report Comprised of national **and regional** authorities and bodies responsible for health technology assessment, **without any financial interests in any type of health technology developer industry or insurance company that may affect their impartiality**, appointed by Member States on an ad-hoc or permanent basis Decisions by consensus, or, where necessary, by **qualified** majority Dedicated sub-groups for joint clinical assessments, joint scientific consultations, identification of emerging health technologies, voluntary cooperation, preparation of the annual work programmes and annual reports, and updates of the common rules and working documents **Support Framework:** Commission: Responsibility to host, oversee and co-chair the meetings of the Coordination Group, **without the right to vote**, provide secretariat, administrative, scientific and IT support, and facilitate cooperation between the Coordination Group, the EMA and relevant Union bodies on medical devices Stakeholder Network: open call and selection process addressed at **patient associations, consumer organisations, non-governmental organisations in the field of health, health technology developers and health professionals. The European Parliament shall have two representatives.** Responsibilities include informational exchanges with the Coordination Group, **feedback on the preparation of the Annual Work Programme** and nominating clinical experts and patients to attend meetings of the Coordination Group as observers	**Member State Coordination Group:** Executive and strategic responsibilities, including an Annual Work Programme and Annual Report Comprised of national and regional authorities and bodies responsible for health technology assessment, without any financial interests in any type of health technology developer industry or insurance company that may affect their impartiality, appointed by Member States on an ad-hoc or permanent basis **Decisions by consensus, or, where necessary, by qualified majority for the adoption of the Annual Work Programme, Annual Report and Strategic Direction** **Decisions by consensus, or where necessary by simple majority for matters of technical or scientific nature (e.g., JCAs, JSCs etc.)** Dedicated sub-groups for joint clinical assessments, joint scientific consultations, identification of emerging health technologies, **development of methodological and procedural guidance.** **Support Framework:** Commission: Responsibility to host and oversee the meetings of the Coordination Group, provide secretariat, administrative, scientific and IT support, **decide of conflict of interest** and facilitate cooperation between the Coordination Group, the EMA and relevant Union bodies on medical devices Stakeholder Network: open call and selection process addressed at **all eligible organisations, in particular** patient associations, consumer organisations, non-governmental organisations in the field of health, health technology developers and health professionals. Responsibilities include informational exchanges with the Coordination Group **and receiving updates on the progress of joint work. The Coordination Group may invite members of the stakeholder network to attend its meetings as observers.**

Joint Clinical Assessments (REAs):	**Scope**: All medicinal products undergoing the central marketing authorisation procedure (Regulation (EC) No 726/2004) Medical devices classified as class IIb and III (highest risk) according to Regulation (EU) 2017/745 and *in vitro* diagnostic medical devices classified as class D (highest risk) according to Regulation (EU) 2017/746 for which the relevant expert panels have provided a scientific opinion **Participation**: Voluntary, for a three-year transition period Mandatory, thereafter **Uptake**: Voluntary, for a three-year transition period Mandatory, thereafter **Methodology:** A common procedural and methodological framework for clinical assessments, procedures for joint clinical assessments and procedures for joint scientific consultations, including distinct rules for medicinal products and medical devices, established by the Commission **Timeline:** Synchronised with market authorisation decision	**Scope**: All medicinal products undergoing the central marketing authorisation procedure (Regulation (EC) No 726/2004), and products not covered by the regulation but **where the health technology developer has opted for the centralised authorisation procedure, and they constitute a major technical, scientific or therapeutic innovation.** Medical devices classified as class IIb and III (highest risk) according to Regulation (EU) 2017/745 and *in vitro* diagnostic medical devices classified as class D (highest risk) according to Regulation (EU) 2017/746 for which the relevant expert panels have provided a scientific opinion **and considered to be a significant innovation and with potential significant impact on public health or health care systems** **Participation**: Voluntary, for a three-year transition period Mandatory, thereafter **Uptake**: Voluntary, for a three-year transition period Mandatory, thereafter Although not allowed to duplicate, Member States can **consider additional clinical data and evidence when necessary to complete the health technology assessment or the overall pricing and reimbursement process, with the obligation to inform the Coordination Group of these intentions and justify the choice.** **Methodology:** A common procedural and methodological framework for clinical assessments, procedures for joint clinical assessments and procedures for joint scientific consultations, including distinct rules for medicinal products and medical devices, established **by the Coordination Group**. **In the case of orphan medicines, there may be determined that there is no substantive reason to support further clinical analysis beyond the significant benefit assessment already carried by the EMA.** **Timeline:** Synchronised with market authorisation decision	**Scope:** All medicinal products undergoing the central marketing authorisation procedure (Regulation (EC) No 726/2004) **and authorised medicinal products for which a joint clinical assessment report has been already published but a new therapeutic indication is introduced.** Medical devices classified as class IIb and III (highest risk) according to Regulation (EU) 2017/745 and *in vitro* diagnostic medical devices classified as class D (highest risk) according to Regulation (EU) 2017/746 for which the relevant expert panels have provided a scientific opinion. **Participation:** **Phased mandatory participation:** **From January 2025, for oncology and advanced therapy medicinal products (ATMPs) and high-risk medical devices and in vitro diagnostics** **From January 2028, for orphan medicinal products** **From January 2030, for all other centrally authorised medicinal products** **Uptake:** **Mandatory obligation to:** 1. **Give due consideration to the published joint clinical assessment reports** 2. **Annex the dossier submitted by the health technology developer to the documentation of the HTA at Member State level** 3. **Annex the published joint clinical assessment report to the HTA report at Member State level** 4. **Not request at the national level information, data, analyses or other evidence that has been submitted by the health technology developer at Union level** 5. **Immediately share through the IT platform referred any information, data, analyses and other evidence with the Coordination Group that they receive from the health technology developer at Member State level** **Methodology:** A common procedural and methodological framework for clinical assessments, procedures for joint clinical assessments and procedures for joint scientific consultations, including distinct rules for medicinal products and medical devices, established by the Coordination Group **Timeline:** Synchronised with market authorisation decision

Joint Scientific Consultations:	**Scope:** Health technology developers may request a joint scientific consultation with the Coordination Group for the purposes of obtaining scientific advice concerning data and evidence likely to be required as part of a joint clinical assessment **Selection:** The Coordination Group shall evaluate joint scientific consultation requests according to the following criteria: 1. the likelihood that the health technology under development will be the subject of a joint clinical assessment 2. unmet medical needs 3. potential impact on patients, public health, or healthcare systems 4. significant cross-border dimension 5. major Union-wide added value 6. the available resources **Timeline:** The Coordination Group shall inform health technology developers on the outcome of their request within 15 days and prepare a report within 100 days. Health technology developers may request that the joint scientific consultation takes place in parallel with the process of receiving scientific advice from the European Medicines Agency for market authorisation.	**Scope:** Health technology developers may request a joint scientific consultation with the Coordination Group for the purposes of obtaining scientific advice concerning **the optimal design of studies to obtain the best scientific evidence, improve predictability, align research priorities and enhance the quality and efficiency of said research, to obtain the best evidence**. **Selection:** The Coordination Group shall evaluate joint scientific consultation requests according to the following criteria: 1. the likelihood that the health technology under development will be the subject of a joint clinical assessment 2. unmet medical needs 3. potential impact on patients, public health, or healthcare systems 4. significant cross-border dimension 5. major Union-wide added value 6. the available resources **7. Union clinical research priorities** **Timeline:** The Coordination Group shall inform health technology developers on the outcome of their request within 15 days and prepare a report within 100 days. Health technology developers may request that the joint scientific consultation takes place in parallel with the process of receiving scientific advice from the European Medicines Agency for market authorisation.	**Scope:** **The Coordination Group shall carry out joint scientific consultations in order to exchange information with health technology developers on their development plans for a given health technology. Those consultations shall facilitate the generation of evidence that meets the likely evidence requirements of a subsequent joint clinical assessment on that health technology** **Selection:** The Coordination Group shall evaluate joint scientific consultation requests according to the following criteria: 1. unmet medical needs **2. first in class** 3. potential impact on patients, public health, or healthcare systems 4. significant cross-border dimension 5. major Union-wide added value 6. Union clinical research priorities **Timeline:** The Coordination Group shall inform health technology developers on the outcome of their request within 15 days. **The Commission shall send the joint scientific consultation outcome document to the requesting health technology developer at the latest 10 working days after it has been finalised**. JSCs on medicinal products may take place in parallel with the process of receiving scientific advice from the European Medicines Agency for market authorisation. **JSCs on medical devices may take place in parallel with the consultation of the expert panels pursuant to Article 61(2) of Regulation (EU) 2017/745.**
Emerging Health Technologies (Horizon Scanning)	**Scope:** Annual study prepared by the Coordination Group on emerging health technologies expected to have a major impact on patients, public health or healthcare systems. The conclusions of the study shall be summarised in the Coordination Group's annual report and be taken into account in the preparation of its annual work programmes. **Process:** Consultative process between the Coordination Group and health technology developers, patients' organisations, clinical experts, the EMA, the Medical Devices Coordination Group (Regulation (EU) 2017/745)	**Scope:** Annual study prepared by the Coordination Group on emerging health technologies expected to have a major impact on patients, public health or healthcare systems. The conclusions of the study shall be summarised in the Coordination Group's annual report and be taken into account in the preparation of its annual work programmes. **Process:** Consultative process between the Coordination Group and health technology developers, patient **and consumer organisations, health professionals,** organisations, clinical experts, the EMA, the Medical Devices Coordination Group (Regulation (EU) 2017/745)	**Scope:** **The Coordination Group shall ensure the preparation of reports** on emerging health technologies expected to have a major impact on patients, public health or healthcare systems**. Reports shall in particular address the estimated clinical impact and the potential organisational and financial consequences of emerging health technologies for national healthcare systems.** **Process:** **The preparation of the reports shall be based on existing scientific reports or initiatives on emerging health technologies and information from relevant sources, including clinical study registers and scientific reports, the EMA, the Medical Device Coordination Group, health technology developers and members of the stakeholder network. The Coordination Group may consult**

			stakeholder organisations which are not members of the stakeholder network and other relevant experts, as appropriate.
Voluntary Cooperation on Health Technology Assessment	**Scope:** The Commission shall support cooperation and the exchange of scientific information among Member States on: 1. non-clinical assessments on health technologies 2. collaborative assessments on medical devices 3. health technology assessments on health technologies other than medicinal products or medical devices 4. the provision of additional evidence necessary to support health technology assessments The Coordination Group shall be used to facilitate the cooperation	**Scope:** The Commission shall support **any further** cooperation and the exchange of scientific information among Member States on: 1. non-clinical assessments on health technologies 2. collaborative assessments on medical devices 3. health technology assessments on health technologies other than medicinal products or medical devices 4. the provision of additional evidence necessary to support health technology assessments **5. clinical assessments of medicinal products and medical devices carried out by Member States** **6. measures relating to compassionate use in clinical practice in order to improve the evidence basis and to create a register for this purpose** **7. the development of best medical practice guides based on scientific evidence** **8. disinvestment in obsolete technologies** **9. the tightening of the rules on clinical evidence generation and its monitoring** The Coordination Group shall be used to facilitate the cooperation	**Scope:** The Commission shall support cooperation and the exchange of scientific information among Member States on: 1. non-clinical assessments on health technologies 2. collaborative assessments on medical devices **and in vitro diagnostic medical devices** 3. HTAs on health technologies other than medicinal products, medical devices or in vitro diagnostic medical devices 4. **the provision of additional evidence necessary to support HTAs, in particular in relation to health technologies for compassionate use and obsolete health technologies** 5. **emerging health technologies with a major anticipated impact on patients, public health or healthcare systems**. The Coordination Group shall be used to facilitate the cooperation
Funding	Union Funding for the work of the Coordination Group and sub-groups Assessor and co-assessors shall be entitled to a special allowance compensating them for their work on joint clinical assessments and joint scientific consultations	Union Funding for the work of the Coordination Group and sub-groups, **stable and permanent, without the direct or indirect funding by developers of health technologies** The Commission may establish a system of charges for health technology developers requesting both joint scientific consultations and joint clinical assessments which it shall use to finance research regarding unmet medical needs or clinical priorities. Such a system of charges shall under no circumstances used to finance activities under this Regulation. Assessor and co-assessors shall be entitled to a special allowance compensating them for their work on joint clinical assessments and joint scientific consultations	**Union Funding for the work of the Coordination Group and sub-groups in support of the work on joint clinical assessments and joint scientific consultations, including the development of methodological guidance, and on the identification of emerging health technologies.** Assessor and co-assessors shall be entitled to a special allowance compensating them for their work on joint clinical assessments and joint scientific consultations.

Appendix Table 2: Comparative Overview of the Commission's Proposal, the EP's Amendments and the Final Version of Regulation (EU) 2021/2282