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Policy Games Large and Small: Explaining the Inclusion of Transferable Data Exclusivity Vouchers in the EU's Pharmaceutical Revision Through Actor-Centered Institutionalism

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ABSTRACT

In the 2025 revision of the EU's pharmaceutical legislation, transferable data exclusivity vouchers were included as a novel incentive for antimicrobial development. In light of considerable controversy around these vouchers throughout the legislative process, this is a surprising outcome. This paper investigates their introduction through actor-centered institutionalism. Based on qualitative analysis of documents and semi-structured interviews, two core contributions result: Theoretically, the paper provides an application of actor-centered institutionalism that defines the institutional context in which actors operate on a small and large scale. Empirically, it shows that this distinction adds nuance to understanding how the vouchers came about: their inception is best explained by actors who played a small game around a policy instrument while falling back on the normative assumptions of a policy field's large game. As a result of this divergence, market logics from the EU's pharmaceutical regulation carried considerable impact on AMR governance.

1 | Introduction

Growing antimicrobial resistance (AMR) poses a grave and imminent threat to health and food systems globally (World Health Organization 2023). Yet, as a crisis, it has often remained overlooked outside of health communities. As metaphors of AMR as a "silent pandemic" of "superbugs" that usher in a "post-antibiotic apocalypse" because of "empty antibiotic pipelines" enter societal discourse (Krockow et al. 2024; Kamenshchikova et al. 2023; Wells et al. 2025), awareness of the need for solutions spreads. In this context, political science has started to grapple with the challenge of AMR. Given the scale of the threat and the stakes involved on the one hand, as well as the reported difficulties in effective governance solutions on the other, an understanding of the political conditions around AMR governance remains crucial to gather political will (see also Pierre et al. 2024; Baekkeskov and Rubin 2024).

The EU has contributed to AMR governance in the agricultural and in the health sector (Deruelle 2021; Jensen 2023). Particularly in the fields of human health care, this has historically focused on soft law and guidance. The pharmaceutical revision agreed in December 2025 adds a novel incentive in the form of Transferable Data Exclusivity Vouchers (TDEV), described as a "world-pioneering measure" by the Health Commissioner. These aim to tackle the spread of resistance by incentivizing pharmaceutical companies to develop innovative antimicrobial medicines. Thus, they add a new instrument to the governance of AMR in the EU. In the provisional agreement on the new pharmaceutical package (December 2025), they stand alongside

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a voluntary subscription model.[1] Due to the voluntary nature of this model and the novelty of the vouchers as a flagship instrument, TDEV takes center stage in incentivizing AMR development within the revised General Pharmaceutical Legislation (GPL). Considering both the importance of effective AMR governance and the controversial reception of these vouchers, this paper analyses their introduction into EU regulation. For that sake, it considers their introduction a "small game" in the context of the pharmaceutical revision as a "big game" and employs actor-centered institutionalism to arrive at transferable insights into the divergences between these games.

To mitigate the occurrence of AMR, the use of antimicrobial pharmaceuticals should be as limited as possible (Klug et al. 2021; Garden 2023; Pierre et al. 2024). This creates a market failure leading to limited innovation of new antibiotics, described in prevalent problem framing as "empty antibiotic pipelines" (Wells et al. 2025). This problem diagnosis privileges market incentives as a solution over public approaches to innovation (Wells et al. 2025). As a novel example of an incentive designed to tackle this market failure, TDEV functions by awarding companies with a year of data exclusivity granted upon the licensing of a novel antimicrobial. The holder can then transfer this voucher to extend the data exclusivity rights of any medicine within their portfolio, or alternatively sell it to another company for that purpose (European Commission 2023c). This second possibility provides a more likely expected use, as existing innovative developments of antimicrobials are based mostly in small biotech companies, who hold limited portfolios and would benefit from selling the voucher to a company with a broader and more expensive portfolio (European Commission 2023a). While financial incentives guiding pharmaceutical innovation towards societal goals are common (for a broader overview, see Panteli and Edwards 2018), these vouchers are globally unique. They build upon the governance of pharmaceuticals and the use of market incentives to support the provision of effective antimicrobial medicines as a public good. Considering their importance within the pharmaceutical revision and within the EU's AMR governance, this paper addresses the research question: How did the inclusion of the vouchers within the EU's Pharmaceutical Regulation come about?

Their introduction within the pharmaceutical revision is surprising from multiple angles. Their approach is globally novel, has not been previously applied, and is thus based on modeling rather than on experience. This novelty is amplified by the fact that other jurisdictions with strong AMR development incentives had, over the years, considered but opted against the option of the vouchers (see O'Neill 2016 in the United Kingdom; or Mossialos 2010 for WHO EURO). Relatedly, in spite of almost universal recognition of the threat of AMR, these vouchers have been met with criticism by stakeholders throughout civil society, Member States, and the European Parliament (see, e.g., Årdal et al. 2024; Berner-Rodoreda et al. 2023; Non-Paper 2022; European Parliament 2024b). Their novelty and the controversy around them therefore provide an empirical puzzle: neither support by stakeholder groups, nor links to previous policies are as strong as expected.

To understand their inception, this paper analyses the policy process behind their inclusion through the lens of actor-centered institutionalism (Scharpf 1997; Schreurs 2024a). As a theoretical framework, actor-centered institutionalism focusses on the behavior of actors within the institutional settings within which they operate (Scharpf 1997; Schreurs 2024a). Specifically, the framework uses the language of orientations to show how actors form their preferences based on subjective assessments of empirics and causal relations (cognitive orientations), of expectations and ideal outcomes (normative orientations), and of relationships and commonalities with other actors (interaction orientations) (see Schreurs 2024a). This terminology is helpful because it provides a broad framework that is theoretically flexible enough to assess which factors are relevant to the explanation of a given situation, and particularly to assess how different empirically relevant factors come together to influence a final policy choice. It is thus well-suited for an inductive, empirically driven assessment of the policy process behind a puzzling policy outcome, as is the goal of this paper. Interestingly, the framework is less specific about what the "institutional context" shaping actor behavior around a policy decision is. This paper argues that analytical leverage is gained when the understanding of context is broadened to carry multiple meanings: In the case of the vouchers, actors were influenced by the institutional context of both the discussions around the vouchers specifically and of the pharmaceutical revision more broadly. Understanding how these "small" and "large" games and the potential discrepancies between them impacted actors throughout the policy process adds nuance to understanding the outcome.

To assess how the inclusion of the vouchers within the EU's Pharmaceutical Regulation came about, the paper draws on document analysis and interviews. The analysis shows the process of negotiation taking place within and between the European Commission, the European Parliament, and the Council around the inclusion of the vouchers. Collected evidence is analyzed through the lenses of cognitive, normative, and interaction orientations that constitute actor preferences in actor-centered institutionalism (see Scharpf 1997; Schreurs 2024a). Crucially, both discussions around the vouchers specifically and around their role in the broader pharmaceutical revision are considered. This dual focus reveals that actors based their preferences on cognitive and interaction orientations that were specific to the case of the vouchers, but on normative orientations that fell back to the broader scope of the pharmaceutical revision. This provides novel insights into the vouchers as an instrument diverging from its wider political context.

Thereby, the paper makes several contributions. First, it provides an application of actor-centered institutionalism that illustrates crucial details about a relevant policy development. Specifically, it argues that the space left open by the framework's relatively limited conceptualization of "context" can be

[1]This allows Member States to opt in to joint public contracts that pay for the availability of antimicrobials rather than their sale. Similar models are described under different names: subscription models, Netflix models, flat-rate models, delinking/decoupling, guaranteed revenue, or more specific terms like "purchase of antimicrobials or purchase of a guaranteed access in the form of 'reservation contract'" (European Commission 2023a, 106).

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used for analytical traction: The process behind the vouchers shows that actors may follow broader or more narrow conceptualizations of what they define as a particular "game." Particularly in a policy field where smaller games are submerged within larger games, these conceptualizations and their divergences add important nuance to understanding the motivations of policy actors. Second, the paper contributes to the literature on health policy making to argue that in such cases, market logics established within the large game are likely to prevail even when they are not well-suited for the "smaller" game around a specific policy instrument.

2 | Theoretical Framework

Actor-centered institutionalism emphasizes the interactions between individual or collective actors and the institutional settings within which they operate (Scharpf 1997). As a theoretical framework, it emerges from rational-choice institutionalism, and is at times submerged therein (see, e.g., Peters 2016). Both depart from the assumption that policy choices are determined by boundedly rational assessments of individuals who are purposeful and strategic, oriented towards goal attainment, while their choices are shaped, and often constrained, by institutions (Scharpf 1997; Schreurs 2024a). These institutions do not fully determine policy outcomes but structure the range of available options and the modes of interaction through which decisions are reached (Maarse 2023). Actor-centered institutionalism thus incorporates both intentional agency and rule-bound behavior, highlighting how actors pursue their interests within complex and interdependent decision-making environments (see, e.g., Maarse 2023). Crucially, policy making outcomes result from the strategic interaction of multiple actors with diverse competencies, resources, and interests, whose preferences are neither fixed nor purely exogenous but shaped by institutional roles and contextual dynamics. While some applications focus on this general premise (see, e.g., Boessen and Maarse 2008), analytical nuance is added when distinguishing between different ways in which actors develop their preferences: Scharpf (1997) discusses the ways in which actors assess available empirical evidence (cognitive orientations), the expectations inherent to the policy context (normative orientations), as well as their roles within an actor constellation in a given institutional setting (interaction orientations) (see Scharpf 1997; Schreurs 2024a).

Yet, categorizing which influences came together in what way to form actor behavior is still complex and relies on additional simplification. Scharpf (1997), in the original framework, draws heavily on game-theoretic elements to formalize actor behavior into theoretically grounded types. However, game theory comes with its own assumptions, and Schreurs (2024a) diagnoses that "a specific, applied ACI literature has not emerged" (p. 7) and recommends that "ACI may need to become less game-theoretic and more actor-centric" (p. 8) to reach its full potential within empirical analysis. Developing applications of actor-centered institutionalism from a more actor-centric point of view thus redirects focus to more inductive, context-specific operationalizations of a broader range of empirical material that gives insight into how actors might have interpreted their role. Helpful guidance to a middle ground between simplification and complexity is provided by the principle of institutional primacy, by which an institutional approach is used as far as possible and empirical assessments of actor behavior in a given context are then added only to explain remaining puzzles (Schreurs 2024a; Iskandar and Bandelow 2026). To arrive at a reasonable application of the framework to the analysis, a close consideration of the framework's subdimensions is thus necessary – for the sake of this paper, adapted to the realm of EU health policy with its institutional constraints.

Considering the three orientations explicitly within their institutional context reveals additional nuance to actor-centered institutionalism. As a theoretical framework, it is not conclusive on how to define the context of a given policy "game" (Scharpf 1997), but leaves this definition up to the case knowledge of the researcher. In using actor-centered institutionalism for an "interaction-oriented analysis of public policy [to] unpack the chains of causation behind an outcome of interest" (Schreurs 2024a, 4; see also Goetz 2020), researchers have a tendency to broaden their lens: focussing on "'big questions' and large-scale transformations" (p. 5) allows capturing where actors focus most of their resources, interact the most, and exhibit the strongest preferences. However, understanding the process behind a particular outcome of interest, like the vouchers, depends on a specific analysis of the interactions within a particular institutional setting (Schreurs 2024a). This specificity also allows for research which increasingly introduces its own nuances on what constitutes relevant understandings of an institutional context (see, e.g., Goetz 2020, on the distinction between institutions and organizations in the study of political executives). With this backdrop, this paper argues that applying actor-centered institutionalism to "smaller" cases within a larger policy game proves a helpful middle ground to capture the analytical leverage of the framework.

The inclusion of TDEV within the broader context of the EU's pharmaceutical revision provides an example of such a smaller case. To make sense of their puzzling role, the process leading up to the outcome of introducing the vouchers in the EU's pharmaceutical revision is investigated. For that sake, this paper follows Scharpf (1997) in his modular approach to defining how actors in a policy process form their preferences in response to the context around them. This gives focus to the way that actors respond to the available empirical evidence (cognitive orientation), to the expectations within a given context of policy making (normative orientation), and to their interactions with one another (interaction orientation). The following sub-sections, therefore, present cognitive orientations, normative orientations, and interaction orientations, with the explicit purpose of placing them into the context of EU health policy making. Thereby, it emerges that this context plays out in a smaller "game" (introducing TDEV) within a large-scale policy process (revising the EU's GPL for the first time in 20 years). Articulating how these two levels diverge provides additional nuance to the ways in which actors "play" smaller games, while accounting for ways in which "'big questions' and large-scale transformations" (Schreurs 2024a, 5) play out in smaller arenas.

An analytical approach dedicated to capturing this duality is particularly relevant in EU health policy. Public health in the

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EU is based on a narrow treaty mandate of shared competences, so that actions are structurally constrained (see, e.g., Brooks and Guy 2021). Yet, a broad field of literature has established that the influence of policies based on other legal mandates have had a considerable indirect influence on health (Boessen and Maarse 2008; Greer 2014; Brooks and Guy 2021; Lamping and Steffen 2009; Greer et al. 2024). Applications of internal market law and regulation have long shaped the regulation of health-relevant sectors such as tobacco (Boessen and Maarse 2008) or healthcare and services (Lamping and Steffen 2009). More recently, Greer et al. (2024) suggest looking at EU health policy through the lens of social determinants of health. This allows for a more holistic look at how factors relevant to health are shaped by EU policy emerging from different contexts. Overall, this lengthy history of indirect health policy suggests that EU health policy makers show considerable experience in finding indirect ways for progress in public health. Such strategies may create divergences between small policy "games" and the bigger policy "games" that form their context. Applying actor-centered institutionalism helps to understand how actors act in these situations. Thereby, this paper provides an example of an application of actor-centered institutionalism suited to a type of case which is likely to gain prevalence in EU policy making.

2.1 | Cognitive Orientations: (Dis-)Agreeing on Evidence

Actor-centered institutionalism posits that development of preferences responds at least partly to the actors' "cognitive orientations" (Scharpf 1997; Schreurs 2024a). This captures actors' empirical knowledge of a situation and of the anticipated effect of possible courses of action. In accordance with Scharpf (1997), cognitive orientations are formed as a composite of assessments of the policy issue, the status quo, and the possible paths of action. The goal here is not to assume omniscience of all involved actors, but rather to develop a reasonable assessment of the knowledge shared in the discourse of the institutional context under investigation. This also captures how actors respond to new ideas or new experiences (Scharpf 1997). Empirically, this dimension thus requires assessments of what actors were talking about when debating their decisions – information which is likely to be available from documents (Scharpf 1997). Applying this sub-dimension to the case of the vouchers thus depends on two questions critical to capture how evidence determines actors' cognitive preferences in the policy making behind the vouchers: The assessment of AMR as a policy problem, on the one hand, and the assessment of the vouchers as the best solution thereto, on the other hand.

In principle, it is broadly agreed that policy-making should make use of the best available evidence (Cairney 2019). However, more critical analyses of evidence-based policy making have also long acknowledged that ideal-typical, linear use of gold-standard evidence poses insurmountable challenges in real-world policy-making, so that political actors should instead strive for practicable solutions (Parkhurst 2017; Cairney 2019; Strassheim and Kettunen 2014; Löblová 2018). The vouchers as a novel policy instrument, for example, provide a case in which policy makers must act in the absence of evidence on their efficiency as a solution to AMR (see Cairney 2019). The availability of evidence as a facet in preference formation is therefore contingent on the nature of the policy instrument: As in the case of the vouchers, it is not always complete and conclusive, and actors may disagree on the evidence presented to them.

In contrast, problem pressure on AMR is widely agreed upon based on the empirical evidence provided. As a result, the need to tackle AMR is widely recognized in the EU and thus becomes part of the institutional setting in which actors operate. In spite of practical challenges (Time 2021; Kirchhelle and Podolsky 2022), soft-law and advocacy initiatives prevail, and agencies for food safety, medicines, and disease control have advocated on AMR within their respective remits for years (Deruelle 2021; Baekkeskov and Pierre 2024). Council Recommendations on AMR launched in June 2023 as part of the Pharmaceutical Package and signed off by the Member States without further controversy (Council of the European Union 2023) further show awareness and political will. Additionally, AMR is often governed through related, more institutionalized fields, such as agriculture and animal welfare, in which policy instruments towards the same goal are "harder" (Deruelle 2021). Focussing on agricultural policy, Jensen (2023) describes that AMR has "become an important EU policy area" (p. 65) to the point that "the EU can be viewed as a driver in the struggle to control AMR" (p. 67). As the problem of AMR and the need for its governance are, therefore, prevalent in discourse throughout the EU, actors should be guided by a preference to tackle it as a problem, even in the absence of clear-cut solutions.

2.2 | Normative Orientations: Facing Expectations

In addition to empirical evidence, actors base their preferences on "normative expectations addressed to the occupants of given positions" (Scharpf 1997, 64). These expectations are not necessarily formal, but shared between participants of an interaction. They can refer either to the rules that permit or constrain actions in a given setting or to the way different courses of action may reach intended purposes (Scharpf 1997; Schreurs 2024a). Particularly this latter form of normative expectations is likely to be more stable and linked to the defining role of actors (Scharpf 1997; Schreurs 2024a), but both still respond to context. Crucially, this subdimension captures more of the goals actors follow when engaging in a policy process, rather than the means they follow towards this ideal outcome (Scharpf 1997; Schreurs 2024b). To tackle AMR in the context of the pharmaceutical revision, actors face normative expectations to position themselves between health and markets, and to choose a policy path that corresponds to that preference. This is because it is inherent to pharmaceutical regulation to stand at a crossroads of health policy and competitiveness, which create different and often even contradictory expectations of policy action (Hancher 2015; Greer et al. 2024). In contrast, AMR emerges as a highly complex policy problem with diverse influences of different policy domains (Time 2021; Kirchhelle and Podolsky 2022).

Within EU health policy, the GPL carries specific institutional conditions. In its current form, pharmaceutical regulation is

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based on an explicit Treaty mandate and has been thoroughly institutionalized through the European Medicines Agency (EMA) "to the extent that this is now one of the most regulated sectors of the European market" (Greer et al. 2024, 127). Importantly, this still depends on a clear division of competence that leaves the Member States to decide on pricing, reimbursement, and provision of medicines (Hancher 2015; Syrett 2020). Mainly, the role for market-making is more entrenched than in other health policy areas (Hancher 2015; Geyer 2011; Karokis-Mavrikos 2025). This reflects historical path dependencies, as the pharmaceutical policy unit was only moved to DG SANTE from the Directorate for Enterprise and Industry in 2010 (Vestlund 2014), as well as spillover effects of competition law in the case of pharmaceutical pricing (Danieli 2020). As a result, the powers of the EU are strictly limited to the safety of medicines, with the moment of regulatory approval as the core to EU competence (Hancher 2015; Syrett 2020). Karokis-Mavrikos (2025) has also shown how industry-oriented policy actors continue to hold a determinative position in the EU's pharmaceutical revision, which other policy entrepreneurs must counter. Other cases show that this power is not absolute, but hard to overcome (Geyer 2011; Brooks and Geyer 2012). The institutional boundaries of the EU mandate and the prevalence of industrial power thus shape both the policy-making context and the expectations which actors therein face.

This understanding of the context poses the question of how well these comparatively rigid institutional boundaries suit the policy problem of AMR. Literature on AMR governance usually stresses the need for collective governance (Pierre et al. 2024) and cross-boundary collaboration (Time 2021). Research from different angles has diagnosed that current approaches to governance are failing and have called for paradigm shifts in the interest of a "just transition" (Varadan et al. 2025). For example, Wells et al. (2025) have shown how a market-based framing of AMR as a policy problem privileges market-based solutions: determining that AMR is caused by a lack of innovative antibiotics creates the expectation that it shall be tackled through industry incentives and market-making measures. They explain this as a "failure" and argue for a "diverse and equitable innovation era [...] beyond the self-imposed limits of the 'empty antibiotic pipeline' imaginary" (p. 22). Kirchhelle and Podolsky (2022) show more broadly why AMR provides an "awkward fit" with existing institutions of health governance. Similarly, Weldon and Hoffman (2024) have called for a paradigm shift to govern AMR as a "socioecological challenge" (p. 1170) to account for its long-term nature and systemic embeddedness. Fulfilling such demands for equitable, sustainable, and systemic approaches to AMR creates normative expectations within which actors shall act that do not necessarily correspond with those of the pharmaceutical revision. These clashes make it interesting to understand the normative orientations that result from actors trying to position themselves within a field of competing expectations.

2.3 | Interaction Orientations: Who Is in Charge?

Tackling policy issues within different realms does not only impact on the normative expectations that actors face, but also on the ways in which they relate to each other and the roles they take within these constellations (Scharpf 1997; Schreurs 2024a). Actors develop their preferences not in isolation, but in relation to the preferences of one another. Moreover, they also adjust the strategies used to achieve their preferences. Within these interaction orientations, Scharpf (1997) distinguishes between those conditions that are "sufficiently stable and interpersonally known" (p. 84) and those that result from "subjective redefinitions of the objective interest constellation" (p. 84). This distinction reflects the underlying assumption of actor-centered institutionalism that interactions are to some extent institutionally pre-determined. For example, it is inherent to the ordinary legislative procedure in the EU that the European Commission acts with the right of initiative and introduces a proposal, while the European Parliament and the Council act as co-legislators. This is of less empirical interest than considering how actors use these roles to strategize around each other within institutional bounds (Scharpf 1997). Therefore, the final dimension of interaction orientations is treated more inductively than the previous ones.

Following the previous dimensions, such an inductive assessment shall reflect expected differences between actor communities in AMR governance and in pharmaceutical governance. The actor community in the EU's AMR governance has been subject to considerable research aiming to understand its governance challenges. Such research recently confirms that the EU has "a strong 'epistemic community' where senior public servants working with AMR know each other" (Pierre et al. 2024, 4050) (see also Deruelle 2021). However, within this community, coordination problems remain because collective action is contingent on the use of agency, which in turn remains impeded by the heterogeneity inherent to the community: Different Member States work with different problem pressures and different levels of resources, with inconclusive effects (Pierre et al. 2024). In the field of pharmaceuticals, the actor constellation is much more established and clearly dominated by the pharmaceutical industry and its affiliated groups (Geiger and Bourgeron 2025; Greer et al. 2024; Karokis-Mavrikos 2025). For a comprehensive understanding of the introduction of the vouchers as an AMR tool in the pharmaceutical revision, an empirical assessment of interaction orientations is therefore critical. This shall inductively show how policy makers from either community develop their preferences and their strategic choice of a course of action in the tensions between the problem of AMR and the context of the pharmaceutical revision.

3 | Research Approach

This paper analyses how TDEV were included in the EU's pharmaceutical revision. For that sake, it describes evidence on the political process behind their inclusion in the form of a detailed case study (Gerring 2012). This procedural understanding is theoretically embedded in the cognitive, normative, and interaction orientations that make up actor preferences according to actor-centered institutionalism (Scharpf 1997; Schreurs 2024a). As the revision of the GPL is a rare and important occurrence (Karokis-Mavrikos 2025), detailed knowledge of the dynamics that underlie it is highly relevant. Moreover, the vouchers are an example of a small game played

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within the context of this bigger game, thus providing a chance to nuance a dual application of actor-centered institutionalism to both contexts.

3.1 | Case Selection

TDEV serve as a policy instrument designed to tackle AMR through the pharmaceutical legislation. They provide an interesting object of investigation for multiple reasons: First, in their aim to tackle AMR, they respond to one of the most pressing policy problems in public health at the moment (World Health Organization 2023). In line with their importance, they were subject to broad debate within the health policy community of the EU (see, e.g., Årdal et al. 2024; Berner-Rodoreda et al. 2023). Second, they provide a novel way of designing incentives to guide pharmaceutical innovation into socially desirable forms, thus responding to a similarly pressing problem of market failures in pharmaceutical innovation (see, e.g., Panteli and Edwards 2018; Gotham et al. 2021). This entails broader relevance to the discourse around value-based pharmaceutical systems (see, e.g., Varadan et al. 2025). Third, they are part of the first pharmaceutical revision in 20 years, which provides a key text in the EU's health acquis and thus a significant guidepost for how the EU thinks about medicine and care (Karokis-Mavrikos 2025). Finally, their introduction provides a theoretically interesting case in which a policy context that is designed towards an institutionally narrow aim (safety of pharmaceuticals for human use) serves as the basis for the very broad policy problem of AMR.

Although the threat of AMR is almost universally recognized, these vouchers have been met with criticism. Scholarly commentary focuses mainly on two dimensions: First, their possible application to high-priced, high-selling medicines raises concerns about associated risks to healthcare payers' budgets (Årdal et al. 2024; Berner-Rodoreda et al. 2023; Anderson et al. 2022; Van de Wiele et al. 2023). Berner-Rodoreda et al. (2023) specifically warn that these risks could be borne in an arbitrary fashion, while Årdal et al. (2024) highlight possible inequitable effects. This poses additional risks to access to biosimilar products (Årdal et al. 2024; Berner-Rodoreda et al. 2023), which create competition for a medicinal product after its patent runs out. Second, uncertainty remains around their anticipated effectiveness. Concerns arise around their ability to ensure practical access to new antimicrobials (Berner-Rodoreda et al. 2023; Anderson et al. 2022), particularly in light of current minimal development efforts (Årdal et al. 2024) and previous experiences with limited effects of market entry reward systems (Anderson et al. 2022). Most of the time, these concerns are based on a broad distrust against an incentive that detaches the value of the vouchers from the value of the developed medicines (Anderson et al. 2022; Årdal et al. 2024; Van de Wiele et al. 2023). What draws these critical comments together, however, is their repeated emphasis on the necessity for additional European policy action on the issue of AMR. It remains interesting to investigate why this search landed on the vouchers.

Within the pharmaceutical revision, the vouchers respond to a demand for a strong pull incentive that tackles the broken market of antimicrobials (Gotham et al. 2021; Ridley et al. 2024) and thus aim to solve the issue of an "empty antibiotic pipeline" (Wells et al. 2025).[2] The debate around them mirrors long-standing debates that have been held at the international and national level (O'Neill 2016; Mossialos 2010). A precedent is found in the priority review vouchers (PRV) in the United States, which reward the licensing of a medicine for neglected diseases with a voucher that allows a future application for authorization with the FDA to be fast-tracked, irrespective of its fulfillment of fast-track criteria (Aerts et al. 2022).[3] However, the variation of TDEV is more suited to the overall logic of the pharmaceutical revision: In the EU, speed of reviews is rather tackled through changes to the broader system of authorization pathways. Incentives are instead granted through intellectual property rights (European Commission 2023c; Karokis-Mavrikos 2025). The vouchers thus sit as an innovation within the broader context of the pharmaceutical revision, and understanding the ways in which they are adapted to this policy context provides an interesting angle.

Considering the backlash that TDEV have faced, as well as their place within the EU's policy landscape, confirms them as a peculiar case. Their inception responds to considerable problem pressure emerging from the threat of AMR. However, it provides a novel and innovative approach to this issue, which stands out in the context of EU health policy-making. A more detailed understanding as to why the search for a policy solution to AMR in the pharmaceutical revision resulted in the vouchers thus depends on a detailed empirical assessment of the policy process.

3.2 | Data

Data consists of 86 documents as well as 6 interviews. A comprehensive corpus of documents was collected from a range of sources: First, documents from the Legislative Observatory of the European Parliament were considered for inclusion if associated with procedure file 2023/0131(COD) or otherwise related to the proposal for a Regulation, including those identified through snowball sampling. A range of additional documents was obtained from Access to Information Requests by the author (24 documents, particularly on the Council) or by other researchers (23 documents). These were supplemented by a thorough search for additional gray literature published in the form of position papers or statements. Twelve documents were selected to be included in the database because they included

[2]Overall, the EU already provides considerable funding towards push incentives, which support companies upfront towards the development of medicines, as well as support schemes directed at knowledge-sharing, such as the Innovative Medicine Initiative. This provides support for collaborations towards common priority goals in the interest of supporting innovation with a focus on areas of high unmet need (Panteli and Edwards 2018; Faure et al. 2018; Garden 2023) but also smaller, more specific initiatives targeted, for example, at ensuring development of antimicrobials in the absence of market incentives (Klug et al. 2021; Garden 2023). In the provisional agreement on the pharmaceutical package, the vouchers are also combined with a voluntary subscription model to support AMR development.

[3]Regulatory transfer instruments aiming to guide behavior are also applied in other fields of EU policy, but TDEV are the first to use data exclusivity rights as a currency and the first to use a voucher incentive. Comparable measures rather use permissions or maximum quotas to be traded (such as the Emission Trading Scheme or historical examples in the Common Agricultural Policy).

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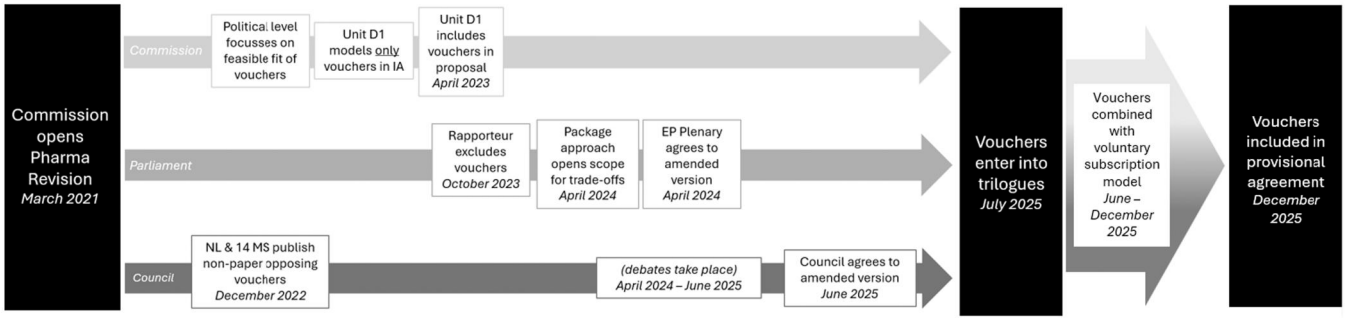


FIGURE 1 | Timeline of policy process behind the vouchers.

direct commentary on the vouchers and referred to the policy context of the EU. As a result of these criteria, most of them were written by EU-level bodies in the time of the Pharmaceutical Revision, although the first reference comes from the Office of Health Economics in 2019. Documents published in languages other than English or German were machine-translated into English.

Interviewees were selected to represent the different EU institutions involved in the decision-making process on the pharmaceutical revision. A total of 25 interview invitations were sent to policy makers with identifiable involvement in the pharmaceutical revision in the European Parliament, the European Commission, and a range of Member State representations, as well as to civil society actors with detailed knowledge of the process. Interviews were conducted with one civil society stakeholders involved in the advocacy around TDEV (online in the lead-up to data analysis) and with five policy makers (in person in Brussels in April 2025).[4] Interviewees were considered to be involved in the revision process based on the analyzed documents or public statements, as well as through snowball sampling.

3.3 | Data Analysis

Data was analyzed in two rounds. An inductive approach was used to build together an understanding of the policy process behind the vouchers as a puzzling outcome. Initially, interviews were transcribed, and documents were screened to identify content relevant to understanding the inclusion of the vouchers. In a second round, data was summarized inductively to arrive at an understanding of the process behind their inclusion. The aim of this analysis was to arrive at a descriptive understanding of the political process within the Commission, Parliament, and Council. As shown in Figure 1, a timeline of more specific steps was derived to hypothesize a detailed understanding of how the outcome of the process ("vouchers included in the provisional agreement on the EU's pharma package, December 2025") came about. This is reported in Section 4.

On that basis, evidence on the behavior of actors is reconstructed using actor-centered institutionalism as a theoretical framework. In the research design, actor-centered institutionalism thus guides an "intensive, context-aware, 'theoretically disciplined' reconstruction of the processes of interest, which will entail a back-and-forth between the gathered empirical material and the development of an explanatory narrative that speaks to the research question(s) at hand" (Schreurs 2024a, 9). This outlines, first, how actors assessed empirical evidence on the problem of AMR and the solution of the vouchers (cognitive orientations), second, how actors responded to countervailing expectations inherent to the policy context (normative orientations), and third, how actors related to each other in this process (interaction orientation).

4 | Results

TDEV emerge in the final text of the Pharmaceutical Regulation as a key instrument to address the important issue of AMR. Yet, a description of the policy process shows opposition at every step of the way. In constructing the proposal for the pharmaceutical revision, the Commission first explicitly mentioned the need for a targeted AMR incentive in the Roadmap of March 2021 (European Commission 2021). In line with this, interviewees largely indicate first coming across the idea during the Commission's public consultation exercises, through surveys, or through consultation workshops. This consideration of the vouchers as a (viable) policy option for the EU was built on a discourse in which they had already been floating around prior to that. In the agreed text, they are included alongside a voluntary subscription model that functions by providing a baseline payment for the provision of antimicrobials, thus delinking price from the amount of antimicrobials used and removing the market incentive. While this paper focuses on the novelty and controversial reception of the vouchers, this final result reflects different dimensions of controversy throughout the legislative process. To elucidate this further, the following section outlines first what actors were doing at each step, and second, the orientations behind that behavior.

Within the Commission, the Impact Assessment report from April 2023, with its modeling of the vouchers, guided decision-making. This modeling was conducted in the lead unit and reported in detail in the Impact Assessment (European Commission 2023a, 47), referring to costs and rents for different groups to arrive at the "fair European share" for investments into AMR. However, minutes from meetings of the Inter-Service Steering Group (ISSG) between October 2022 and January 2023 indicate opposition by other DGs: On the one hand, DG ECFIN criticized the lack of data

[4]At this time, the negotiations in the Commission and the European Parliament had been concluded, while negotiations in the Council were ongoing. For more information on the interviewees, see Table S1 in the Appendix.

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on their implementation in light of the high costs, underlining that "it seems that the winners will rather be big pharma and not the companies (SMEs) who will seek to develop new antimicrobials, which makes this instrument potentially controversial" (European Commission 2022b, 6). On the other hand, DG COMP criticized the effectiveness and appropriateness of the measure and possible distorting effects (European Commission 2022a, 2022d). DG GROW built upon this to criticize the risks of disproportionate effects on SMEs (European Commission 2022a). Yet, DG SANTE, as the lead unit, with support from DG RTD, which considered the vouchers the most practical solution (European Commission 2022a, 2022d, 2023d), prevailed in including the vouchers within the proposal.

Even so, as emerging from documents, the design of the vouchers diverged from the modeling already during the drafting of the proposal at the Commission. The initial introduction to the proposed Pharmaceutical Directive also included TDEV as a potential incentive in the field of rare diseases and for pediatric medicines, but this was not considered as a final option (European Commission 2023b). Rather, the final published version included in Article 40, Chapter III of the Proposal for a Regulation focuses on their applicability to "priority antimicrobials," as defined according to a set of characteristics. It further makes the granting dependent on some minimal access and transparency requirements, specifies that transfer may only occur once, sets a limit of 5 years between receipt and application of a voucher, and specifies that a maximum of 10 vouchers may be granted over the next 15 years (European Commission 2023c). This, notably, contains some discrepancies from the modeling in the Impact Assessment (European Commission 2023a), in which the period of possible use after the voucher has been granted was set at 2 years, but changed to 5 years in the proposal. These changes result in further discrepancies between modeling and policy design.

In the European Parliament, controversy around the vouchers largely followed party group lines, with the European People's Party expressing support and the Socialists & Democrats voicing their opposition. Discussions built on the first Committee draft report from October 2023, led by S&D Rapporteur Tiemo Wölken, which had excluded the vouchers and replaced them with the European Medicines Facility as a tool for the financing of innovation towards unmet medical need, including AMR (European Parliament 2023).[5] The text later adopted in Parliament at 1st reading in April 2024 (European Parliament 2024a) emerged from a last-minute joint technical meeting, in which the vouchers alongside other contentious topics from both the proposed Pharmaceutical Directive and the proposed Pharmaceutical Regulation were discussed as "one main political package whereby we don't have an agreement until everything is agreed" (Interview 1). This included an adjusted version of the vouchers, granting staggered durations of transferable data exclusivity dependent on specific conditions for novelty of the antimicrobial, and combining them with increased safeguards. It moreover introduced the idea of a subscription model into the process, alongside other options. Its vote was accompanied by a plenary debate, in which the Rapporteur underlined their preference for a subscription model as an alternative to the vouchers, while other MEPs underlined that they are "grateful that, after initial resistance, in the end a majority approved of the vouchers" (author translation; European Parliament 2024b). Others deemed the vouchers "important" or a "big mistake."

In their final mandate from June 2025, the Council introduced more safeguards aimed at protecting Member State budgets, most prominently a "blockbuster clause" excluding the transfer of the voucher to medicinal products that are particularly expensive.[6] Additionally, the review of the instrument is moved earlier, requirements for an EU-based launch are introduced, and conditions for the transfer of the voucher are specified (Council of the European Union 2025). Thereby, the decisions reflect general opposition to the vouchers voiced by the Member States already early on in the process: A key document was initiated by the Netherlands and published with support from 14 Member States in December 2022, outlining that "the Commission consideration to introduce as reward transferable exclusivity vouchers for novel antimicrobial products is however not supported for several reasons" (Non-Paper 2022). Fundamentally, the signatories agree that the issue of AMR merits a European solution, but advocate for the consideration of alternative mechanisms. Additionally, three Member States who had not listed their support for this non-paper included concerns on their inclusion in their contributions to the European Parliament in November and December 2023. While Czechia and Italy raised concerns about budgetary impacts, pharmaceutical expenditure, and availability of medicines (Parliament of the Czech Republic 2023; Senato della Repubblica 2023), should the vouchers be applied to particularly expensive medicines, the German contribution was supportive of the vouchers while instead warning that they "could only be of limited use due to their current very restrictive design" (German Bundesrat 2023, 6).

This step-wise narration highlights that TDEV in the pharmaceutical revision emerge from a controversial co-legislation process. Yet, this necessitates some further explanations as to why the Commission proposed them, why they were not replaced throughout the process, and why they remained key to the provisionally agreed text alongside the voluntary subscription model. In line with the theoretical framework of actor-centered institutionalism (Scharpf 1997), focus is placed on cognitive, normative, and interaction orientations.

4.1 | Cognitive Orientations: (Dis-)Agreeing on Evidence

Cognitive orientations of actors responded to two facets of evidence: On the one hand, repeated references to the importance of AMR show that evidence on its threats created considerable pressure that policy makers could not ignore. Overall, actors were in agreement that the pharmaceutical revision shall

[5]In the recitals of the draft report, this is described as a "mission-oriented R&D facility" to be established as an independent agency, thus allowing for a necessary "paradigm shift." Its envisioned tasks include "conducting research and developing novel antimicrobials as well as [...] other areas of unmet medical need, to support the Union to overcome market failures." (European Parliament 2023, Recital 78c).

[6]The first idea for this criterion was formulated to say that the application of the vouchers is not allowed unless "the marketing authorisation holder demonstrates that the annual gross sales of that medicinal products in the Union during any of the preceding four years have not exceeded 490 million euros" (Council of the European Union 2025, 93). The final text continues to use this cut-off.

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contain a policy measure on AMR and repeatedly underlined that dedication in interviews and position statements (e.g., Non-Paper 2022). This pressure to act thus became part of the institutional environment of the policy process behind the vouchers. On the other hand, evidence on the vouchers was more limited. This raised considerable discussion and opened space for disagreement.

As the main evidence guiding the selection of the vouchers for the proposal, the Impact Assessment provided detailed modeling of the economic impacts of the vouchers as an incentive for the development of antimicrobials (European Commission 2023a). In addition to their technical feasibility, the Report presented a wide range of stakeholder contributions into a synopsis report as evidence of their political feasibility. This identified the pay-or-play model, in which pharmaceutical companies that do not hold antimicrobial medicines in their portfolio must contribute to collective funding for AMR research, and the vouchers as the highest-ranked policy measures on AMR. However, the report noted, "low inter-stakeholder agreement" (European Commission 2023a, Annex II: 14) on both measures. Crucially, industry favored the vouchers, and civil society organizations favored the pay-or-play model. Yet, the Impact Assessment modeled only the vouchers, with the pay-or-play model compared "just conceptually," concluding that "it failed, not on the numbers. It failed on the political feasibility" (Interview 2). Relatedly, a chapter on possible future initiatives on AMR describes a possible guaranteed revenue scheme akin to the voluntary subscription model of the final text (European Commission 2023a, Annex 15: 109). However, the report here states that such a model "will provide access, but may not be big enough to incentivise innovation" (p. 109). Consideration at this point seems to have been that such an initiative should be implemented by HERA separately from the pharmaceutical legislation, rather than drafted into the legal text (European Commission 2023a, 47).

In contrast to work done by HERA, EU JAMRAI, and ongoing pilot schemes for subscription models in England and Sweden (European Commission 2023a, Annex 15: 106–109), it emerges even more clearly that the vouchers were based on less experiential evidence. This is characteristic of policy innovation, yet still poses a challenge and leaves the Impact Assessment to rely largely on modeling. While this model included novel evidence combined in a detailed and well-thought-out manner ("This is something that was very difficult. We needed the model, we needed data [...] We provide the model, we explain, so we were quite happy that we're not, you know, just guessing in the air but have seen some real evidence basically." – Interview 2), the final published version faced mixed reactions from the other actors, with interviewees variably commenting:

> *There wasn't real evidence on why this was going to work. [The Commission] only said basically: 'We think this is the best thing', but they didn't really underline why. And they didn't say why they didn't look into different options. Although we know that there are pilot projects, especially when it comes to subscription model. [...] The Impact Assessments are supposed to give us different policy options, but if you only look into one option, there's no variety. [...] That they didn't even take the time to look into it, at least one more, is not acceptable [...].*
>
> – Interview 1

Or:

> *I think the Commission did their best in gauging what voucher might cost and they presented it very well [in the relevant bodies]. But I think they did their homework well, but still, it hinges on some assumptions, right? So, there are also some Member States that were critical on the underlying assumptions. [...] I don't know what they could have done differently, but it definitely could have helped to have a more complete picture before you. But, on the other hand, we also didn't do any follow-up studies on the alternatives, in all transparency. So, yeah, the Impact Assessment – puh. I don't want to shoot down the Impact Assessment.*
>
> – Interview 4

Resulting from gaps in the evidence on the vouchers, further political discussion occurred between actors with differing cognitive orientations. For example, the Regulatory Scrutiny Board (RSB) gave a negative opinion on the proposal in July 2022. This opinion criticized, amongst other things, that "it is not clear how the market launch conditionality and the transferable exclusivity vouchers for AMR products will work exactly. Possible counter-effects affecting the access-affordability tradeoff are not sufficiently assessed" (European Commission 2023e). Specifically, they requested more detailed evidence on design parameters, on the intended effects of the vouchers on research output for antimicrobials, and on effects regarding the medicines to which the voucher is finally applied (European Commission 2023e). While the changes from this version to the final version cannot be traced based on published documents, interviewees indicate that changes to the technical content were limited, and resolution of the conflict instead depended on the political level:

> *After the negative, they escalated, so that was a meeting between [the Commissioner responsible for the RSB, the Director General for Health, and the Commissioner for Health]. [Director General for Health] just explained: Yes, this is what our policy, this is what we want politically. It may not be the same as you see what the EU has to do, but these are our reasons. And then it was all fine, so we had to resubmit. I think I changed, like ... added two paragraphs or something to the whole stack. And then it was ooh, positive, super nice ... [...] So, there is in SecGen actual people who do the analysis, you know, only to technical guys, reading it and flagging the issues. And you know, we were in contact with that, and they said, no, it's wonderful. It's super nicely done. But still, you know, you got a big list of comments on the negative and then, for the next time, it was easy positive. Thank you.*
>
> – Interview 2

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Overall, it emerges that the development of preferences based on cognitive orientations was not straightforward in the case of the vouchers. An explanation of policy makers' behavior based on an assessment of empirical evidence does not explain the outcome of the vouchers. Instead, the focus on the model in the absence of experiential evidence invited considerable political questioning by different respondents. As a result, stakeholders appear to have drawn on other sources to develop their preferences.

4.2 | Normative Orientations: Facing Expectations

The assessment of problem pressure to develop an effective solution for AMR creates the expectation that actors must do something, but cognitive orientations do not suffice to explain why the vouchers were chosen as a solution. Instead, normative expectations within the decision-making process also played a role: a policy action must respond to the rules of its institutional settings and fulfill the actors' normative intentions. In the case at hand, policy makers thus had to find a solution that could, first, fulfill the function of incentivizing pharmaceutical innovation, and, second, adapt to the institutionalized logics of EU pharmaceutical regulation. The final result shows that the Commission drew on the PRV scheme in the United States, while adapting to the use of exclusivity periods as a currency in a way that is more established in the EU's licensing system. This indicates a fit between the design of the vouchers and the overall design logic of the pharmaceutical revision. As was reported in interviews:

> *As a pull incentive, the voucher is not a new idea. The United States use vouchers for priority review of certain medicines in the US already, which also was a first seed of thought of how we could be using vouchers in general as a pull incentive. [...] we also had the idea of: how do we use the EU incentive system, so regulatory protection, as an incentive to make companies do stuff that we want them to do. Together with the idea of the voucher as a priority review that happened in the U.S. before. Putting those things together, gave the idea for this voucher.*
>
> – Interview 3b

However, despite this adapted fit, the vouchers faced considerable backlash from stakeholders whose expectations were not met. Policy makers were aware of considerable criticism from Member States (Non-Paper 2022) and civil society organizations working on access to medicines and on AMR. Yet, these debates address the vouchers as a policy solution in general, rather than the discussion around the design of the vouchers. This indicates a fit between the design of the vouchers and the overall design logic of the pharmaceutical revision. Notably, for neither the initial modeling and design nor the consequent alterations, documents indicate a strong role for AMR specialists. More explicitly, interviewees indicated that individuals took the lead on AMR during the drafting of the Impact Assessment, but that this "was not very relevant for the model" (Interview 2). In determining whose expectations to prioritize, policy actors were thus less specific in their discussion around the vouchers, but rather focused on designing an instrument that fit the parameters of the pharmaceutical legislation.

Instead, the vouchers play a part in the pharmaceutical revision's overall balance of competing interests. Specifically, they were designed as a counterweight to instances in which industry feels over-regulated. Thereby, the introduction of the vouchers allowed the European Commission to fulfill the normative expectation to balance the interests of different sides, in this case, corresponding strongly to fulfilling the expectations of the pharmaceutical industry. The nature of EU legislation means that the industry may at times face a higher burden of regulation than Member States, as elaborated by an interviewee:

> *And basically, we put the burden [for equitable access] on the Pharma companies, because we can regulate Pharma companies and we cannot regulate Member States in legislation. [...] Whereas [the vouchers] was rather coming from the Pharma industry suggestion and we said, okay, to be in balance, we take this on in the final package, and there the Member States have to pay more, SMEs get the reward.*
>
> – Interview 2

Governing AMR through the pharmaceutical framework puts an emphasis on research and development incentives as a key instrument. This creates normative expectations of the involved actors to balance competing interests. Focusing on the vouchers responds to the rules and levers of the pharmaceutical framework in the EU in a way that alternative incentive options might not. In this way, the normative orientations of the overall game of the pharmaceutical revision seem to be more determinative of the preference formation in the smaller game around the vouchers. Preference formation around the vouchers themselves appears limited, as one of the interviewees summarizes: "That's like the main thread of the voucher. We don't like it, it's the only thing we have" (Interview 4).

4.3 | Interaction Orientations: Strategizing Around the Vouchers

Previous sections have shown that the actor's preference for the voucher was cognitively shaped by considerable problem pressure, but not by conviction of their effectiveness, as well as by the overarching wish to suit the institutional constraints of the pharmaceutical revision and balance competing expectations in the pharmaceutical revision. Additional nuance emerges when understanding how actors relate to each other and form their roles by anticipating the behavior of one another. Seeing as cognitive and normative orientations on the vouchers, specifically, were inconclusive, it remains unclear who might function as a driving actor behind their inclusion. Analysis indicates that the Commission, European Parliament, and Council rather waited for one another to take ownership of an alternative incentive for the development of innovative antimicrobials, while using the vouchers as an opening for discourse on the problem of AMR. This responds to the strength of broadly perceived problem pressure in the cognitive domain, as actors

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were largely guided by a shared understanding that the threat of AMR meant that some response to AMR had to be included in the pharmaceutical revision.

Principally, the Commission holds the right of initiative in EU policy making and introduced the vouchers into discussion. However, including TDEV in the final text did not seem certain. Rather, those involved in the debate seemed to see the voucher proposal as an opening of space for discussions around AMR. Interviewees reported surprise at their stability:

> *We went into it at the very beginning that, okay, it has a very, very thin lifeline. [...] We know it's sub-optimal. But you propose an alternative. If you Member States dislike it, put forward something that works. But if you only say it's not working and we don't do anything for AMR, then no, we insist, it remains [...] And for some magical reasons, it survived until this point [...]. I always say to people that look, it may not fly, but the longer it lives, the longer we talk about it, and people just realize and cannot just leave it. Okay, if not this, we have to do something to make a pull incentive for AMR developers because this is a broken market and just, you know, keeping this knowledge on the surface. It is a broken market, it is the threat you have to do something about. You know, that already helps.*
>
> – Interview 2

> *It's a good catalyst. It's a good way to – to at least get the discussion going. So, whether we end up with a voucher or a subscription model or whatever, the outcome of the Pharma package negotiations will be that we're doing something.*
>
> – Interview 4

Indeed, the vouchers fulfilled this role and opened space for compromise or for an alternative. Documents reveal that co-legislators considered different ideas throughout the legislative process. Presented with the initial proposal, two main strategies remained in their interactions with the Commission and with each other: First, alterations to the voucher design, and second, suggesting alternative incentives.

In the European Parliament, alterations were made by introducing safeguards and criteria for novelty (European Parliament 2024a). Moreover, consideration for alternatives started with the inclusion of a Medicines Facility and milestone payments in the First Draft of the Committee Report from October 2023 in place of the vouchers (European Parliament 2023). In the final report from March 2024, milestone payments were included alongside the vouchers as an alternative (European Parliament 2024c). This approach is likely to reflect a strategy of including different options for Member States to choose from during the following Council negotiations, as was reported in an interview:

> *And when we meet [Member States], we also tell them: listen, choose your poison because whatever happens you need to pay for it. So, if you say the voucher is it at the end of the day, be our guest and we say yes. But if you already say hell no, then look into milestones, look into subscriptions, look into all of the different possibilities that there are, because you need to say yes to one of the things. Otherwise, we won't have a deal.*
>
> – Interview 1

In the Council, the same strategy options apply. First, some amendments were introduced so that the final version of the mandate for negotiations, concluded in June 2025, includes a "blockbuster clause." This clause limits the transfer of the vouchers to medicines above a certain threshold as a limit to their cost at the health system level (Council of the European Union 2025). This idea is first observed in the comments from the Estonian delegation from July 2024, intending to guard against "unpredictable and potentially significant additional costs for the health insurance system" (Council of the European Union 2024b, 23) by suggesting upper limits for turnovers or transaction values, or exclusion of "certain categories of medicinal products" (p. 24). Second, as in the European Parliament, some alternatives were introduced for further negotiations. In November 2024, comments from the Danish delegation also emerged to re-enter the US-inspired PRV into discourse as an alternative (Council of the European Union 2024a, 133–134). Overall, these approaches reflected a shared critical assessment of the vouchers:

> *There's lots of things we don't agree on [...] but I think the opposition to the vouchers was quite broad. And we were also quite aligned in why we thought the voucher wasn't the way to go. Like, we need to do something on AMR. So, that's what discussions [...] have been like, how much do we treat this proposal? How much can we put an alternative on the table? That's what the negotiations have been about so far. Along the way there have been some [actors who] became more vocal and said, well, if we can't work out a proper alternative, then we just need to go with the voucher. We need to fix this for our patients. So, although we don't like it, it's the only thing we have.*
>
> – Interview 4

In the end, Parliament and Council opted against completely replacing the vouchers with an alternative instrument and rather focused on changes to their design. These alterations intend to safeguard Member State health budgets as well as patient access to medicines, but at the same time diverge from the modeling in the Impact Assessment (European Commission 2023a) and thus may change the workings and overall value of the vouchers. This is particularly notable as some actors had already expressed concern whether the vouchers provided a strong enough incentive for the development of antimicrobial medicines (see, e.g., German Bundesrat 2023). Overall, considering the dynamics of the actor constellation around the vouchers reveals considerable relational strategizing. Importantly, these interaction orientations appear to reflect the pressure to tackle AMR. As such, they are again more

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specific to the vouchers and separate from the dynamics of the overall pharmaceutical revision than was the case regarding normative orientations.

5 | Conclusion

In spite of considerable controversy, TDEV have been introduced as a key instrument to tackle AMR in the EU's revised pharmaceutical framework. This paper explains how their position in the provisional agreement came about by considering evidence from documents and interviews through the theoretical framework of actor-centered institutionalism (Scharpf 1997; Schreurs 2024a). For that sake, it considers the decision-making process behind their introduction as its own political "game" played within the context of the pharmaceutical revision. First, it has shown that actors' cognitive preferences for the vouchers were shaped by evidence on the problem pressure of AMR, but less so by evidence on their effectiveness. This gap shifts focus to the explanatory power of normative expectations, which are determined in this case by placing the governance of AMR into the pharmaceutical revision at the crossroads of health and market. In efforts to accommodate the constraints of the pharmaceutical legislation and balance competing actor interests, the vouchers emerge as a fitting proposal. From there on out, it is particularly the interaction orientations that explain the puzzling stability of the vouchers throughout a controversial policy process: actors developed their strategies based on expectations of one another, which were not necessarily fulfilled, and thus resorted to amending rather than replacing the vouchers. Thereby, vouchers result from actor preferences based on cognitive and interaction orientations developed specifically around the vouchers, but on normative orientations developed in the larger scope of the pharmaceutical revision.

The vouchers provide a case in which actor preferences respond to the institutional context of a small instrument within a large policy framework. It is known that the legal basis chosen for EU health policy (in this case, the pharmaceutical legislation) impacts on the outcome and its anticipated public health effects (see, e.g., Boessen and Maarse 2008 on tobacco control or Martinsen 2017 on cross-border patients' rights). The pharmaceutical framework chosen as a legal basis for the vouchers thus carries much of its inherited market logic into its revision (Karokis-Mavrikos 2025). In the messy, multi-dimensional problem of AMR, this leads to a focus on the incentivization of innovation through a market instrument while limiting the potential of other policy instruments towards the same goal. In this sense, the placement of AMR as a policy problem into the realm of the pharmaceutical legislation emerges as a key determinant of the inclusion of the vouchers. While this can plausibly be explained as emerging from the problem pressure of AMR coinciding with the opening of the pharmaceutical revision, a more thorough understanding of the framing and definitions that led to this placement may yield further transferable insights.

Beyond its empirical focus, the paper thereby contributes to the literature on EU policy-making in the field of health and beyond. It shows that an analysis of actions in the "game" around the vouchers must also account for its placement within the bigger context of the pharmaceutical revision. As a result, actor constellations in the struggle around the vouchers are less entrenched. Cognitive preferences dictate a strong desire to act on the policy problem of AMR, but are less clear regarding the chosen path of action. Therefore, normative orientations gain a determinative role. But crucially, these normative orientations respond to the broader scope of the pharmaceutical revision, rather than to the game of the vouchers specifically. In adjusting their strategies to the normative expectations posed to them, actors are likely to prioritize games with a larger scale and high visibility, rather than redefining their role to smaller discussions around individual instruments. Considering Schreurs (2024a) argument that normative orientations are likely to be the most stable over time, this paper highlights that their role is particularly important in policy processes where smaller games on individual measures diverge from their larger context.

This nuance highlights the importance of context in applying the framework of actor-centered institutionalism. The investigation into the process behind the vouchers provided an application thereof that shows that the breakdown of cognitive, normative, and interaction orientations provides nuanced language to discuss how different contextual influences on actor behavior come together in a long policy process. However, it is less clear what should be considered as a "policy context." In this paper, this vagueness is exploited to show that a differential conceptualization of "context" in applications of actor-centered institutionalism can be analytically helpful to show how cognitive, normative, and interaction orientations come together. Viewing discussions around smaller policy instruments in the context of larger initiatives highlights that both might provide different conditions for cognitive, normative, and interaction orientations. These differences add crucial insights to the assessment of how policy makers respond to their institutional environments in a given policy process. Particularly in the field of health, such institutional (mis)fits may be important to understand: Due to its limited mandate and institutional constraints, indirect policy action on different legal bases in addition to or instead of the EU's competence in health is common (Boessen and Maarse 2008; Greer 2014; Brooks and Guy 2021). Actor-centered institutionalism has been applied to such cases (e.g., Boessen and Maarse 2008). Yet, its application to the case of TDEV reveals a strong added value in its dual application to highlight divergences of smaller games contextualized within larger games.

The conclusion of this paper draws attention to the fit between instruments and their broader policy framework, thus nuancing how this fit determines actor preferences within a given institutional setting. It emerges, first, that normative orientations gain in importance, and second, these normative orientations are more likely to respond to the big-stroke policy games rather than adjust to smaller games played within their scope. Applying actor-centered institutionalism to understand the duality of such cases provides a promising explanatory angle towards puzzling policy outcomes. In the field of EU health policy and beyond, such cases are likely to occur again: not all problems fit neatly into the boundaries of EU mandates. Particularly when EU policy becomes more polarized and controversial, indirect policy making may become a more promising

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strategy. In light of this trend, it becomes ever-more important to consider how such placements of policy instruments determines policy outcomes.

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Conflicts of Interest

The author declares no conflicts of interest.

Data Availability Statement

Transcripts of the interviews cited in this study are available, upon reasonable request, from the corresponding author. The data are not publicly available due to their containing information that could compromise the privacy of research participants.

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