Health Technology Assessment and Health Care Reimbursement in the European Union: Permissive Dissensus and the Limits of Harmonization through the Backdoor

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Abstract Member states have consistently limited the European Union's competences in the area of health care reimbursement. Despite these efforts, there has been a slow but steady tendency toward harmonization of a key tool in reimbursement decision-making: health technology assessment (HTA), a multidisciplinary evaluation of "value for money" of medicines, devices, diagnostics, and interventions, which provides expert advice for reimbursement decisions. This article examines the origins of this paradoxical appetite for harmonization as well as of the dissensus that has, at the moment, somewhat stalled further integration in HTA. It finds that the prointegration neofunctionalist "permissive dissensus" is still present in decision making on HTA but potentially offset by dissensus or outright opposition from key actors, including member states and the medical device industry. These actors are able to decipher the potential consequences of highly technical issues, such as HTA, for national systems of social protection. Despite that, they have little interest in politicizing the issue, potentially opening the door to integrative policy solutions in the future.

Keywords health technology assessment, European integration, health care reimbursement, permissive dissensus, harmonization

Health care makes up a large part of European Union (EU) member states' spending, about 7% of member states' public budgets on average, making it the second most costly government expenditure item after social protection and a major cost center of the welfare state (Eurostat 2018, 2019). Of this sum, non-negligible amounts of money are spent on pharmaceuticals, ranging from 7% in Denmark to 41% in Bulgaria (OECD 2019), and an additional 5–10% on average is spent on medical devices and

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diagnostics (MedTech Europe 2018a). Rising costs of new health technologies and the increasing need or demand for care can only be expected to intensify pressures on health systems in the future. These trends create an increasingly tangible dilemma for EU member states: face growing health care budgets or ration patients' access to care.

The EU has little competence in telling member states how to solve this dilemma, despite general tendencies toward a greater EU involvement in health care via a spectrum of instruments ranging from information sharing to recommendations under the European Semester procedure and judicial review (Greer, Jarman, and Baeten 2016; Vollaard and Martinsen 2017; Vollaard, van de Bovenkamp, and Martinsen 2016). The EU has a key role in authorizing new medicines to be sold on the internal market, notably via the centralized procedure for marketing authorization of medicines run by the European Medicines Agency (EMA). It also regulates the entry of individual medical devices and diagnostics on the single market by a decentralized procedure of conformity assessment ("CE marking"), although its regulatory role for devices and diagnostics is weaker than for drugs, even after the 2017 reform (Allan, Joyce, and Pollock 2018; Altenstetter and Permanand 2007). Crucially, once a drug or a device has been authorized, the EU has no grounds to tell member states if their health system should pay for it.[1]

Indeed, to harmonize which treatments and services EU countries should cover could be construed as harmonizing social policy through the backdoor. This is something governments have, in the past, explicitly tried to prevent: article 168(7) of the Treaty on the Functioning of the European Union explicitly states that the EU must respect member states' responsibilities for the organization and delivery of health services and medical care, including decisions on the allocation of resources for these areas. Much of the controversy surrounding the Cross-Border Healthcare Directive (2011/24/EU) and high-profile rulings of the Court of Justice of the EU, such the *Elchinov* case (C-173/09), also concerned the degree to which member states were driven toward harmonizing the scope of benefits they provide (Hatzopoulos and Hervey 2013).

Despite the EU's limited competence in the broad area of health care financing, there has been a slow but, until very recently, steady tendency toward harmonization of a key tool of reimbursement decision making: health technology assessment (HTA). This article analyzes this paradoxical

1. The Transparency Directive (2004/109/EC) provides some rules for pricing and reimbursement decision processes in the member states, but these are limited to procedural requirements, notably timelines for member state authorities to follow when evaluating pharmaceuticals.

development as part of discussions on greater integration of Europe's social policies in a highly technical, expert-led policy area, which could nonetheless have tangible repercussions on the lives of European citizens and patients.

Health technology assessment is an evaluation of future "value for money" of health technologies—a category that includes not only devices and diagnostics but also pharmaceuticals and surgical and other interventions.[2] Most EU member states have some form of national or regional HTA bodies, which typically provide expert advice on reimbursement decisions to health care payers or make authoritative decisions on funding themselves (Löblová 2016). National and regional HTA bodies have been collaborating, with the European Commission's support, since the 1980s (Drummond 1987), and in 2018 the commission issued a proposal for a regulation on HTA that would prevent member states from developing national HTA reports where European ones exist (European Commission 2018a). This proved contentious; at the time of writing of this article (August 2019), the Romanian presidency had failed to find a compromise in the council before the May 2019 European Parliament elections and the future of the regulation was unclear. The current legislative limbo surrounding HTA makes it difficult to draw definitive conclusions about the policy's likely importance for European health and social policy.[3] It does, however, provide an opportunity to examine key actors' positions, which may offer lessons about preferences for a more active Union role in social matters. This article therefore asks: Is there appetite among key European actors for harmonization in HTA? If so, where does it come from? And conversely, where does potential resistance originate?

In previous work (Greer and Löblová 2017), we described the surreptitious ascent of HTA on the European agenda as a case in point of the validity of the neofunctional logic of integration in the EU agenda-setting process: the appetite for integration comes from supranational elites, created with strong support from the commission, who are biased toward proposing EU-level solutions. In this article, as the HTA dossier moves through the legislative procedure, I suggest the neofunctionalist "permissive dissensus" is still, at least partially, present at the decision stage. Supporters from the commission and expert networks, created during the past 30 years thanks to EU funding, systematically push for harmonization of key aspects of HTA. Contrary to the expectations of postfunctionalist

2. In fact, most HTA reports in Europe focus on pharmaceuticals (Chamova 2017).
3. As of May 2020, the HTA dossier is still unresolved.

and new intergovernmentalist theories of European integration, increasingly Euroskeptic publics have so far not acted as major constraining forces on further harmonization of HTA. Instead, a potentially plausible explanation for the fragmented appetite for harmonization of HTA, to be confirmed in further research, might come from national health care payers or national HTA experts as well as parts of the health care industry.

In the following sections I briefly present the article's conceptual framework and methods. Next I present the developments in the field of HTA at the EU level and key actors' positions. I then discuss the possible origins of the observed dissensus. The article concludes with reflections on the implications of the developments of HTA for the fate of social Europe.

HTA as a Case of Permissive Dissensus?

Before the publication of the commission proposal for an HTA regulation (COM(2018) 51 final), HTA was the perfect illustration of how the neofunctional integrative logic still matters for the setting of the EU's policy agenda (Greer and Löblová 2017). Specifically, the three streams that feed into agenda setting—the problem, policy, and politics streams (Kingdon 1984)—are biased in favor of identifying European-level problems and solutions, leading to EU legislative proposals that tend to call for more harmonization.

The bias could be readily explained by neofunctionalist theories of European integration as resulting from a functional spillover, created by interconnected problems in an increasingly interconnected Europe, or a cultivated spillover, created by elites socialized into thinking at the European level (E. B. Haas 1958; Niemann 1998; Schimmelfennig 2014). It presented more of a puzzle for the postfunctionalist approach (Hooghe and Marks 2009), which argues that prointegrative forces may have well led to harmonized policies during the pre-1990s era of permissive consensus when elites pursued further integration in a context of benevolent indifference of their populations, but not in the following times of constraining dissensus, when member states' electorates regularly impose limits on their governments' integrative tendencies. Taking the examples of HTA and communicable disease control in the EU, we proposed that we are, in fact, witnessing permissive dissensus, in which the ongoing neofunctional logic of proposing prointegration policies at the EU level is disconnected from (and stronger than, at least in some cases) increasingly integration-sceptic electoral preferences of European voters (Greer 2013; Greer and Löblová 2017).

Now, as the HTA dossier moves through the motions of the ordinary legislative procedure in the council and the Parliament, it is worth asking how prominent these neofunctionalist dynamics are at the decision stage—a question we hinted at earlier: "Neofunctionalism is working well to explain integration through agenda-setting and alternative specification, in processes as low salience as HTA and as high salience as rights to health care and fiscal governance. A constraining dissensus need not necessarily materialize. . . . *If it is at work, it is at work in the decision stage*" (Greer and Löblová 2017: 409; emphasis added).

This is not to argue that the Kingdonian multiple stream politics of agenda setting should be extended to analyze the decision stage. It is more likely that the politics of the decision stage may be better explained by more established approaches, such as issue bargaining in the Council of Ministers, lobbying, and negotiations within the Parliament. For the purposes of this article, this is in any case immaterial—it is too early in the HTA story to draw conclusions about the politics of its decision making. What we can do, however, is qualify the kind of dissensus (or perhaps consensus) we are able to observe at the moment.

The European integration literature describes several kinds of dissensus: Liesbet Hooghe and Gary Marks's postfunctionalist constraining dissensus, the neofunctionalist permissive dissensus, and the new intergovernmentalist destructive dissensus, in which European governments—when faced with functional pressures for more integration and Euroskeptic publics—engage in redirecting maneuvers that ultimately endanger the stability of the EU (Bickerton, Hodson, and Puetter 2015; Hodson and Puetter 2019). Unhelpfully for the still unfolding topic of HTA, the conceptualizations of all these different dissensuses are to a large degree defined by the outcome of the decision phase. Hooghe and Marks's (2009: 5) constraining dissensus can be observed when dissensus restricts further integration—they oppose the early "years of permissive consensus, of deals cut by insulated elites"—to a constraining dissensus between elites and an electorate ever more aware of European integration issues after the Maastricht Treaty. The neofunctionalist permissive dissensus happens when integration prevails despite potential reticence (Greer 2013)—as does the destructive dissensus of new intergovernmentalism, which is additionally characterized by its normatively negative consequences for democracy (also noted in Greer and Löblová 2017).

The various kinds of dissensus differ, however, in where the central disagreement is located. Constraining dissensus is situated in the member states, whose governments respond to electoral pressures from increasingly

Euroskeptic publics. Destructive dissensus is located in the disequilibrium between these publics and their governments, who are forced by functional pressures to look for new ways of increasing integration while avoiding popular backlash, including, notably, the creation of de novo arm's-length bodies instead of delegating powers to the commission (which in turn practices a form of voluntary self-censorship of grand integrative proposals). Finally, permissive dissensus can be found at the level of European elites, whose freedom to come up with (and quite likely to implement) integrative policies remains relatively unrestricted despite growing Euroskepticism of European voters.

In what follows, I present the potential sites of dissensus among key actors' positions on the harmonization of HTA.

Methods

This exploratory analysis is based predominantly on publicly available documents. Primary sources include legal documents, for example, European Parliament committee reports or contributions of national parliaments, identified via the European Parliament Legislative Observatory (European Parliament n.d.); stakeholder responses to the European Commission consultation on HTA (European Commission n.d.); and official position statements and press releases available on key stakeholders' websites. Secondary sources included specialized trade press and selected national health care and general media. Specifically, I ran Google News searches on HTA in English, Czech, German, and French, and searched the *Politico.eu* archive between January 2018 and August 2019. Finally, this research was informed by a handful of informal conversations with Brussels policy actors in 2018–19. Rather than a comprehensive set of formal semistructured interviews with a purposive sample of stakeholders, these conversations aimed at identifying salient dimensions and important documents in the debate on EU-level HTA. For this reason, they are not explicitly referred to in the following text.

HTA at the Decision Stage

As a multidisciplinary, evidence-based evaluation of the clinical, economic, social, ethical, legal, organizational, and other aspects of new health technologies, health technology assessment eventually influences reimbursement decisions in European countries. Sometimes this is done directly, as in the case of the most famous HTA body worldwide, the English

National Institute for Health and Care Excellence (NICE) (Benoit and Gorry 2017), and sometimes indirectly, as in the German Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG), which provides recommendations on the technologies' value for money to statutory health insurance funds, which are then used in price negotiations with manufacturers.

With such a clear link to allocation of resources in health care, HTA attracts important interests. At the national level, these are mainly the HTA experts themselves, the pharmaceutical and medical device industry, health care payers, and selected high-ranking civil servants (Banta 2003; Löblová 2018b). In contrast, clinicians and their professional societies, as well as patient organizations and the general public, are relatively uninterested in HTA at the national level as a result of the policy's low salience compared to other, more pressing problems in health care (Löblová 2018b). These dynamics are broadly replicated at the EU level, perhaps with the possible exception of patient organizations, who play a more significant role in Brussels than in some European capitals. In the following paragraphs, several actors emerge as key for the HTA legislative dossier: the commission and HTA experts as the most important policy entrepreneurs initiating and promoting the policy; the European Parliament, the pharmaceutical industry, EU-level patient associations and clinicians as relatively enthusiastic but slightly more cautious supporters; and the member states, health care payers, and the medical device industry as key opponents.

The Cheerleaders

HTA Experts

HTA experts have played a vital role in establishing HTA as the dominant tool of reimbursement decision making of the past 20 years. United in national, international, and later also European networks, they lobbied national decision makers for the adoption of HTA in individual countries, with varying success (Löblová 2018a). At the EU level, they formed early collaboration networks, supported by the European Commission, in the mid-1980s (Vella Bonanno et al. 2019).

These networking exercises have so far culminated in the EUnetHTA—the European network for HTA—a network of public and nonprofit HTA bodies from the 28 EU countries plus Norway, Switzerland, and Ukraine, counting currently 81 members (EUnetHTA 2019a). The EUnetHTA started in 2006 as a three-year commission-sponsored project and continued in

three consecutive joint actions, cofinanced by the member states in 2010–12, 2012–15, and 2016–20. The EUnetHTA's goals and outputs involved primarily the development of common methodologies and toolkits as well as capacity building in member states with fewer HTA experts (EUnetHTA 2008, 2019a).

The EUnetHTA has been crucial to defining not only the boundaries of HTA, still an emerging field, but also the limits of EU activity in HTA. A case in point is the development of the so-called EUnetHTA Core Model: a trademarked cookbook-style "tool to support European collaboration in producing and sharing HTAs" (Lampe et al. 2009: 18). The Core Model of "Full/Comprehensive HTA" included nine "domains" that should be analyzed in HTA reports for individual technologies: the health problem and current treatment/diagnosis, description of the technology under assessment, its safety, the benefit it provides ("clinical effectiveness"), its cost and economic effectiveness, as well as its ethical, organizational, social, and legal aspects. In later updates to the core model, only the first four domains were proclaimed of interest to the EUnetHTA; ethical, organizational, social, and legal aspects, along with cost and economic factors, were described as prerogatives of national HTA decisions (EUnetHTA 2018a).

Since 2012 the EUnetHTA has produced dozens of common reports (called "rapid relative effectiveness assessments") that focus exclusively on the first four, clinical domains. Through joint assessments, the EUnetHTA experts demonstrated that EU-level cooperation on HTA was technically feasible. Their uptake by member state HTA bodies, however, has been limited. The EUnetHTA, as well as the commission, recognized this as a problem, but rather than portraying it as a sign that Europeanized HTA was not, in fact, useful to the member states, the low uptake was framed as "duplication of efforts among member states"—a problem of its own, which required EU-level legislative action (DG Sante 2017).

The EUnetHTA also engaged in an interesting case of rebranding. Originally, simply *the* European collaboration on HTA, the network's branding changed after the Cross-Border Healthcare Directive established the "Article 15" HTA Network in 2013. Instead of transforming the existing EUnetHTA structures into the Article 15 Network, member states nominated ministry of health officials to the new network. The EUnetHTA, in turn, was reframed as the "scientific and technical" arm of European collaboration on HTA, emphasizing its expertise and neutrality (in contrast to the "political" Article 15 Network) (European Commission 2013). They offered seemingly uncontroversial, technocratic tools of evidence-based governance to tackle the problem of resource allocation in health care.

Correspondingly, the EUnetHTA has not published any formal position regarding the commission's proposal. In line with theories of bureaucratic politics, however, we could expect the organization to fight for self-preservation and portfolio and budget maximization (Niskanen 1973). Indeed, in September 2018, the EUnetHTA's newsletter contained the following discussion of the proposal, suggesting just that the

> *EUnetHTA, as always, remains neutral*, *but* our work through three Joint Actions and the contributions of our 81 partner organizations and institutions is the basis of future cooperation. While the future of the HTA Proposal is uncertain*, there is a very stark reality that will most likely happen if consensus cannot be formulated: there will be no Commission funding for European HTA cooperation post 2020.* It remains to be seen what will become of the work of our partners, or the substantial efforts of the EUnetHTA Secretariat to build a lasting framework for cooperation. *However, no agreement seems a waste of genuine, well-intentioned, and dedicated European cooperation.* HTA cooperation produces and will produce very tangible benefits not only for patients but also improve the quality and sustainability of health systems when Europe needs them most. (EUnetHTA 2018b; emphasis added)

In the summer of 2019, the network published an additional statement clarifying its views on their "Understanding of EUnetHTA HTA," whose first two points seem to speak directly to member states' fears of European HTA's supplanting national reimbursement decision making: "Assessments should *inform* decision-making. Assessments *are not* decision-making processes themselves" (EUnetHTA 2019b; original emphasis).

Despite these high-level statements, the EUnetHTA is not a monolithic body. On the contrary, disagreements among its members about the network's future mission can be expected. Among national and regional HTA bodies in Europe, there are stark differences in methodologies, competences, and capacity (Allen et al. 2013; Barham 2018; Chamova 2017). For instance, some bodies (most notably the English NICE[4] but also the Polish HTA agency) emphasize cost-effectiveness in its assessments, while others (most notably France) put comparatively greater emphasis on the technology's added therapeutic benefit than on its cost. The agencies also differ

4. NICE and the United Kingdom more generally have been rather absent from the HTA debate due to Brexit, potentially giving the commission more leeway than if NICE, with its international reputation and expertise, had been involved and backed by a committed Euroskeptic government (Greer and Löblová 2020).

in parameters such as rates of discounting or involvement of patients and other stakeholders during the assessment process. Without public minutes of EUnetHTA meetings, any disagreements within this realm of epistemic politics are hypothetical.

One hint is, however, provided by a 2013 report on future HTA collaboration based on interviews with more than 15 representatives of national HTA bodies (Ecorys 2013). Without giving specifics, the report highlighted the divisions between small and large member states (mostly copying the divide between established HTA bodies and those with limited capacity), where large, older national HTA agencies (such as NICE, Germany's IQWiG, or France's Haute Autorité de Santé) had "no immediate interest in transferring resources and know-how to other countries" (44). As we will see at the member state level, this division may have well been relevant in 2019.

European Commission

The commission has been consistently promoting an EU-level HTA. This goes back to its long-standing interest in HTA. The commission first mentioned HTA as part of its political priorities in its 2004 communication (European Commission 2004: 11). Since then, it has continued to provide concrete financial support to EU HTA, primarily by funding the EUnetHTA but also by proposing an article on HTA in the 2011 Cross-Border Healthcare Directive (2011/24/EU).

The eventual mention of HTA in the directive is rather restrained: article 15 of the directive established a "voluntary network connecting national authorities or bodies responsible for HTA designated by the Member States" without going into more detail. In parallel, it also specified that collaboration on HTA "shall not interfere with Member States' competences in deciding on the implementation of [HTA] conclusions," harmonize laws on HTA, or interfere with member states' pricing and reimbursement processes. This was a conscious strategy by the commission: compared to the main issue of reimbursement of cross-border care, HTA was a technical topic of relatively minor interest and limited contention, on par with, for example, e-health or cooperation on rare diseases (Greer and Löblová 2017). Implementation of article 15 was similarly subdued, with the commission hosting the new "political" network and the EUnetHTA carrying on with its knowledge exchange and networking without much change.

The 2018 regulation proposal marked a change of approach, with the commission suggesting a more daring policy. The commission identified, relatively uncontroversially, three "problems" the legislation aims at addressing: (1) "impeded and distorted market access" of health technologies across EU countries as a result of differing national HTA processes, which "contribute to . . . lack of business predictability" and "can contribute to delays and inequalities in availabilities of innovative health technologies for patients"; (2) "duplication of work for national [HTA] bodies" and "inefficient use of resources," again negatively affecting business and patients' access to innovation; and (3) "unsustainability of [EU-level] HTA cooperation" (European Commission 2018a: 1–2). The first problem provides justification for the commission to act on the basis of its internal market competence, while the remaining two refer to the Union's supporting competence in ensuring a high level of protection of public health. Avoiding duplication has long been present in the commission's framing of its activities on HTA, included already in Directive 2011/24/EU, as was making sure a cooperation into which the EU has already invested millions of euros continues. Both had been presented multiple times, notably, by the EUnetHTA (e.g., Kristensen et al. 2009).

The bone of contention of the proposal concerned the so-called mandatory uptake of joint assessments. Institutionally, the commission stopped short of proposing an independent HTA agency, an option that had been repeatedly suggested, only to be discarded as unrealistic, since the 1990s (Drummond 2003; Ecorys 2013). It did not propose to add an HTA competence to the EMA (due to opposition of some stakeholders but possibly also partly as a consequence of Brexit and the EMA's international move). Instead, it suggested to establish a "Member State Coordination Group on Health Technology Assessment," composed of national representatives, which would oversee joint work of expert subgroups, equally nominated by the member states. This was a pragmatic and potentially also economical option—EUnetHTA's Joint Action 3 budget of EUR 20 million established a low-cost baseline (DG Sante 2017).

The expert subgroups would develop "joint clinical assessments" for all centrally authorized medicines and selected devices and in vitro diagnostics. Joint assessments would include the first four domains of the EUnetHTA core model. "Nonclinical" domains, particularly cost-effectiveness, budget impact, or ethical consequences, would be excluded from mandatory common assessments due to concerns by "public authorities, experts as well as industry representatives" (DG Sante 2017). Methodologies for clinical assessments at the EU level, but also at the member state level, would be harmonized by a delegated act (adopted by the commission).

Joint assessments were to be subject to "mandatory uptake": once a joint assessment is carried out at the EU level, member states would be free to develop their own assessments of the nonclinical domains but would not be allowed to reevaluate the clinical aspects of the technology in their own national procedures. The commission argued that if national uptake of joint clinical assessments was to remain voluntary, the impact of EU-level HTA collaboration on "duplication of efforts, increased efficiency gains and improved business predictability for industry" would be limited (European Commission 2018b: 60).

This newly aggressive approach might have been a calculation to anchor future negotiations closer to more harmonized outcomes, based on the commission's cultivated spillover bias favoring integrative policy solutions, notably on issues with strong constituencies and large sunk costs. It is also possible, though, that the commission's audacity was slightly disproportionate to the importance of HTA for health in the Union. Instead, it might have had more to do with bureaucratic politics—having been stripped of consumer issues, as well as of the medical devices and diagnostics regulations, in the 2014–19 Juncker Commission, HTA became one of the largest dossiers for the new, smaller commission Directorate-General for Health (DG SANTE). Directorate-General SANTE might have therefore decided to "go big or go home" with the HTA dossier, attempting to show its continued importance for the future, post-2019 commission.

The Cautious Fans

European Parliament

The European Parliament has been in favor of the commission's HTA proposal. In October 2018, the Parliament adopted the dossier in its first reading by 576 votes (56 against, 41 abstentions) (Wheaton 2018c). Its amendments, nevertheless, included several notable changes compared to the commission's proposal, which were not necessarily met with universal praise.

Negotiations within the Environment, Public Health, and Food Safety (ENVI) committee, headed by the Socialist and Democrat rapporteur Soledad Cabezón Ruiz, resulted in a move to limit patients' and medical experts' right to contribute input to draft joint assessments compared to the original commission proposal (Wheaton 2018c). This was, predictably, met with opposition from patient groups (Wheaton 2018e). Little is known publicly about the reason for ENVI's amendment, but the amendment continues by mentioning conflicts of interest, which was a concern for payers

(though payers themselves were not given a say in the joint assessment process in the ENVI amendment) (ESIP 2018a). A counteramendment, proposed by the European United Left-Nordic Green Left group, was rejected (Wheaton 2018e).

Less controversially, the right-wing European People's Party (EPP), represented by the long-time Brussels health policy figure Françoise Grossetête, proposed last-minute changes to the Coordination Group voting rules, which were accepted in the Parliament plenary vote: the original commission proposal stipulated consensus or simple majority and ENVI proposed two-thirds majority, but Grossetête's amendment suggested qualified majority. In what perhaps supports the hypothesis of epistemic politics driving some of the HTA decision making, another EPP health policy member, the German Pieter Liese, "said the move was not designed to placate larger countries like France and Germany [but that] population size 'strongly coincides with the expertise' on HTA" (Wheaton and Oroschakoff 2018). Alternatively, concerns over expertise could be seen as a front for realpolitik anticipation of council divisions.

The Pharmaceutical Industry, Patients, and Doctors

The pharmaceutical industry has been, on the whole, supportive of Europeanized HTA. A number of European trade associations uniting big and small pharma issued a joint position "generally welcoming" the commission's proposal as having "the potential to contribute to expedite patients' access to medicines in Europe" (AESGP et al. 2018). The European Federation of Pharmaceutical Industries and Associations (EFPIA 2011), the association of large manufacturers of original drugs, had argued for a number of years that a single HTA procedure would save time and resources and lead to a greater predictability for their market access plans. A single European clinical assessment, as opposed to the more than 28 required by national and subnational HTA bodies and payers, could save company resources, leading the industry to "strongly support the requirement to apply and not repeat joint clinical assessment reports at the national level" (AESGP et al. 2018). EFPIA was the pivotal player here, as the commission proposal stipulated that joint assessments would apply only to new and important medicines approved via the EMA centralized authorization procedure, leaving generic and biosimilar drugs out of its scope. The industry had two key asks: that nonclinical domains be excluded from the scope of EU-level HTA (EFPIA 2017; Gyldmark et al. 2018) and that manufacturers are allowed to hold "joint scientific consultations"—meetings with

regulators and national HTA bodies on the details of scientific and evidentiary requirements before they submit their dossier (EFPIA 2017). Both were reflected in the commission's proposal.

Patient organizations have also been in favor of mandatory uptake, "warmly" welcoming the commission's proposal as "ambitious" (EPF 2018: 30). Unequal access to treatment, including new medicines, was noted as one of the key policy issues for the European Patients' Forum (EPF) (EPF 2017). European HTA as proposed by the commission, that is, excluding cost, ethics, and so on, is unlikely to remedy this situation, but the EPF (2017: 19) clearly saw it as a first step: "We believe that the definition of common standards on quality and procedural aspects would mitigate if not eliminate imbalances and inequalities in access to innovative technologies and ensure an improvement in patient involvement in HTA."

In other words, the central problem of today's health policy in the Union for the EPF was not "duplication of efforts" or "increased scientific collaboration," as the EUnetHTA and the commission would suggest, but a lack of harmonized social policy (and potentially redistribution of wealth at the EU level). For the EPF, harmonization of the less controversial—scientific and procedural—aspects of HTA could eventually help tackle this issue, or at the very least not hinder future efforts.

Other patient and consumer associations were also in favor of European HTA, albeit with different foci. The association for rare disease patients, EURODIS, expressed concerns about joint assessment requirements presenting an "excessive burden" (Wheaton 2018e)—a concern shared by the association of small and medium pharmaceutical companies EUCOPE (Wheaton 2018a) but dismissed by the European Consumer Organisation (BEUC), which warned against a "less rigorous approach for medicines which treat rare diseases" (Wheaton 2018e). Unsurprisingly, patient organizations have been united in their reaction to the Parliament's amendments limiting their say in the joint assessment process (e.g., ECPC and EAPM 2018).

On this point, medical professionals have been more complacent. After the Parliament vote, cardiologists' and respiratory disease specialists' associations stated, "We expect that the decision not to include scientific experts as full members of the Coordination Group will not preclude . . . collaborative effort" (ESC and ERS 2019). The European Society of Cardiology (ESC 2018) has been one of the few professional associations consistently vocal on (and supportive of) EU HTA, including favoring mandatory uptake of joint assessments. In general, doctors have been rather quiet

about HTA, which may reflect both the relative lack of lobbying power in Brussels and their prioritization of other issues at the national level (see Löblová 2018b).

The Opponents

Member States: Governments and Parliaments

Member states have expressed dissatisfaction with the commission's proposal several times. In May 2018 parliaments of Germany, France, Poland, and the Czech Republic issued reasoned opinions arguing that the commission's choice of the internal market as a legal basis for the regulation was inappropriate and that the proposal, in consequence, violated the principle of subsidiarity (Deutscher Bundestag 2018; Parliament of the Czech Republic 2018; Sejm of the Republic of Poland 2018; Sénat 2018). The Bundestag, in addition, argued that the new rules could lead to a delay in availability of new health technologies for German patients, who currently benefit from the fastest and highly comprehensive access to medical care in Europe (Deutscher Bundestag 2018). In other words, the Bundestag expressed a concern that unified procedures could lead to an equalization of access of care across Europe (as EPF hoped)—which would almost inevitably be a "leveling down" for German patients.

Of more serious concern for the future of the policy was a subsequent letter from health ministers from Bulgaria, the Czech Republic, France, Germany, and Spain, in December 2018. In it, this potential blocking minority took a stance against mandatory uptake of joint clinical assessments and expressed concern about "the 'strong role' of the Commission 'as the final decider on clinical assessment content,'" as proposed by the outgoing Austrian presidency (Wheaton and Jennings 2018). This suggested a reconfiguration of member states' alliances since the (admittedly lower-key) negotiations about the Article 15 HTA Network in 2013. With the HTA proposal, some of the fault lines between core and periphery remained, but the division between large and small member states became blurred.

Crucially, no large member states have gone on record as strong supporters of harmonized HTA—among documented supporters are the Portuguese and Irish parliaments (Assembleia da República Comissão de Assuntos Europeus 2018; Houses of the Oireachtas Joint Committee on Health 2018) and Estonia (Wheaton 2018b). The commission alludes to "a clear orientation" on HTA adopted by member states representatives in the

Article 15 HTA Network in 2014, and it cites three distinct sets of council conclusions (on innovation, personalized medicine, and pharmaceutical systems) referring to coordination on HTA between 2014 and 2016 (DG Sante 2017: 5). The contrast between countries' endorsement of HTA as part of larger health policy debates and their resistance to the commission's concrete proposal would suggest an evolution of countries' positions between the agenda setting and the decision stages.

Apart from subsidiarity concerns, two additional inputs may have played a role for the member states: lobbying against EU HTA from the medical device industry (see below) and resistance from key national HTA experts or other important national health care actors. The latter would be suggested by the fact that the German Bundesrat put on record concerns about unifying methodologies for future European clinical assessments, similarly to the position articulated by German payers (Bundesrat 2018). Likewise, the head of the German payer association expressed concerns over simple majority voting on joint assessments, leading to an "over-politicized decision-making process" (Collis 2019). The question is whether these concerns originate within the Germany HTA community or within the payers, who could reasonably expect to lose some of their discretionary power as a result of the commission proposal. Without additional data, the influence of epistemic politics on member states' preferences is difficult to estimate, though we can find its traces: input from national HTA experts is formally acknowledged at least by the Irish Parliamentary Joint Committee on Health (Houses of the Oireachtas Joint Committee on Health 2018). This would suggest that for HTA, the influence of epistemic communities (P. M. Haas 1992) may have been a powerful factor in a liberal intergovernmentalist two-level process of preference formulation (Moravcsik 1998).

Health Care Payers

Health technology assessment touches on the core of health care payers' activity; health insurance funds, national health services, and other payers have had a clear position on HTA. Their position was largely critical of the commission's proposal. German statutory health insurance funds have been particularly invested in the debate, arguing during the consultation phase that the current system works well for member states: "Differences in assessment procedures between the Member States lead to different results. The GKV-Spitzenverband does not view this as a problem because

the differences reflect national preferences, social conditions and the specificities of the health systems" (GKV-SV 2017). The European Social Insurance Platform (ESIP), reputed for having close ties to German payers (Wheaton 2018e), advocated for collaboration on HTA to be "driven by the Member States taking a bottom-up, step by step approach" (ESIP 2017: 17), as did the International Association of Mutual Benefit Societies (AIM 2017).

Consequently, there was little payers liked in the commission's proposal (ESIP 2018b). Specifically, the ESIP criticized the role of the commission as a coordinator of the Coordination Group as well as what it termed "premature" engagement of stakeholders in the development of joint assessments, jeopardizing the independence of the scientific process. It took issue with the proposal, in draft article 20, to harmonize HTA methodologies including at the national level (a point that, surprisingly, no other stakeholders focused on). More generally, it disagreed with the proposal's foreseeing a key role for implementing and delegated acts for issues of methodology and procedures. It also noted that manufacturers were not required to provide information on their technologies in the proposal and urged for the regulation to mandate their compliance. Finally, the ESIP was against mandatory uptake of joint assessments.

The ESIP obtained most of its demands in the Parliament's amendments: harmonization of methodologies for national HTA was dropped; stakeholders' role was downplayed (though payers also failed to get a seat at the table); a penalty clause for manufacturers' noncompliance was included; and common methodologies were to apply only to EU joint assessments and would be drafted in line with previous EUnetHTA work by the Coordination Group as an implementing regulation to be endorsed by the commission (European Parliament 2018).

As in the case of national HTA bodies, it is unclear what role payers' positions played in the formation of member state preferences. The ESIP's position paper refers to differing preferences among national payers, which it claims reflect national institutional structures and prior experience with the EUnetHTA (ESIP 2018b). Indicating the intensity of their interest in the issue, German payers published their own detailed reaction to the commission's proposal and Cabezón Ruiz's compromise amendments (GKV-SV 2018). The German position in the council certainly seems to copy their wishes—though given the lack of published opinions of other national payers, it is difficult to judge the level of interest of other payers and their impact on the negotiations.

The Medical Devices Industry

The medical devices and diagnostics industry has been clearly and consistently vocal against mandatory EU cooperation on HTA. The industry had been historically subject to little premarket scrutiny in the EU and, per the industry association MedTech Europe, only about 1% of HTA reports concern devices or diagnostics (Maxwell 2018). The HTA regulation proposal was only one of several new legislative reforms to change this: arguably more important were the Medical Device Regulation ([EU] 2017/745) and In Vitro Diagnostics Regulation ([EU] 2017/746), passed in 2017, which increased evidentiary requirements for marketing authorization and surveillance for large parts of the industry (Allan, Joyce, and Pollock 2018). The commission's proposal on HTA has been relatively easy on medical devices and diagnostics: only technologies selected by the Coordination Group based on their importance (impact on patients or health systems, addressing unmet medical need, having a significant cross-border dimension, etc.) from the riskiest classes of products should be subject to joint assessments. Rapporteur Cabezón Ruiz unsuccessfully sought to include more devices and diagnostics—the Parliament eventually further restricted the scope of devices and diagnostics to technologies "considered to be a significant innovation and with potential significant impact" (European Parliament 2018; Wheaton 2018d).

Even this, though, caused resistance within the industry. MedTech Europe (2017b) has argued for a voluntary, decentralized approach to HTA of devices and diagnostics and proposed their own "modern" alternative. It further argued that "tools other than HTA should be developed" to assess medical technologies (MedTech Europe 2018b: 1), as current HTA procedures had been established for pharmaceuticals and are ill adapted to evaluating other technologies. The latter is an argument with some resonance in the HTA expert community (e.g., Fuchs et al. 2017; Garau et al. 2013); in addition, member states' HTA bodies have less expertise in producing HTA reports for "non-drug technologies" than for pharmaceuticals (Chamova 2017). Part of the industry's opposition focused on the feasibility of dealing with two potential changes to its practices in parallel and asked for a longer transition period. Its key concerns, however, involved delays and additional regulatory burden. It argued that "inappropriately used" HTA could delay the time it takes to get new technologies to patients and increase their costs due to disruption of current business models: as a fragmented industry composed

predominantly of small and medium companies and relying on speedy incremental innovation, timely market access is valued by manufacturers (Maxwell 2018; MedTech Europe 2017a).

As with payers, the degree to which the industry has been united in their position is unclear from public sources. Most responses of device and diagnostics manufacturers to the commission consultation referred to the trade association position (European Commission n.d.). It would be surprising, however, if the largest players did not seize the opportunity to use their greater regulatory affairs and HTA capacity to their advantage (cf. Posner 1974). For instance, Roche Diagnostics, the market leader in in vitro diagnostics, was more open to EU-level cooperation than MedTech Europe (but also, for that matter, than another market leader in devices, Johnson & Johnson) (Johnson & Johnson 2017; Roche Diagnostics 2017). Any divisions could potentially also be reflected in member state preferences in the council.

Discussion

At first sight, health technology assessment is an unlikely topic to advance our understanding of European social policy evolution. It is a highly technical issue; the commission's recent legislative proposal will most immediately affect only a small number of experts who already carry out many of the proposed activities. However, its specialist face is misleading. Through its links to decisions on reimbursement, HTA touches on the eminently political problem of resource allocation in health care. "Technical" issues, such as the choice of which existing therapy a new technology should be compared to, have direct repercussions for which treatments become available to European citizens, how fast, and how much they will cost their health systems. Dissensus on harmonization of these issues would not be without cause.

And dissensus there is. Some stakeholders, most notably German statutory health insurance funds, elaborated their thinking on potential consequences of harmonized HTA for their interests and voiced their opposition. Important member states, including France and Germany, explained their reticence by concerns over subsidiarity. There has also been non-negligible support for harmonization, though: some member states, the commission, and the EUnetHTA have acted as strong supporters of EU-level HTA. Even the European Parliament, which has been split over individual provisions of the draft regulation, voted overwhelmingly in favor of the HTA dossier in general, across party, committee, and national lines.

This broad agreement on the desirability of harmonized HTA suggests at least some of the dissensus around HTA is permissive—Brussels elites, and much of the HTA epistemic community cocreated by the commission in the EUnetHTA, keep on proposing and later endorsing integrative measures. In the case of HTA, these proposals are likely to be induced by cultivated, rather than functional, spillover: the main justification for European HTA has consistently been to "reduce duplication of efforts" rather than address a clear threat of an impending catastrophe for human health or livelihood, as was the case for instance in the euro crisis (e.g., Bickerton, Hodson, and Puetter 2015; Schimmelfennig 2014). Perhaps the only functional pressure that could be improved by harmonization was faced by the pharmaceutical industry, which could gain economies of scale and which was familiar with regulation at the EU level from its experience with the EMA. Its support for the commission's HTA proposal is thus in line with traditional neofunctionalist expectations.

But dissensus should not be minimized—the question is where it originates. This is unlikely to be in electoral politics, as the constraining dissensus approach would expect. Beyond the general rise of Euroskepticism, the concrete issue of HTA did not mobilize masses or step out of the pages of Politico's specialized *Morning Health Care* newsletter. The topic was not politicized in any member state, even though the potential for politicization exists: several actors have been conscious of the potentially far-reaching implications of Europeanizing HTA scientific standards and outputs. Only one EU-level patient association has claimed these implications as a desirable outcome: it saw harmonized HTA as a step toward the harmonization not only of the rules and standards for HTA but also of the care patients across member states have access to. All other actors have steered clear of potential controversy of linking HTA to the welfare state.

The dissensus surrounding HTA does not seem destructive in the sense of new intergovernmentalism. First, while some governments were the clearest opponents of harmonization of HTA, they have (to date) not sought solutions that would "redirect" (Hodson and Puetter 2019) integration toward more opaque arrangements than traditional integration. This could well be because of a lack of functional pressure—there is little need to compromise on an issue that is not strictly necessary. Second, the commission did not follow the new intergovernmentalist self-restraining logic. On the contrary: by proposing mandatory uptake of EU output by the governments as well as harmonization of HTA methodologies and procedures even for national processes, it presented an openly integrationist pitch. Certainly, there are limits to its vision: it was careful not to overstep

the limits demarcated by article 168(7), by suggesting to link European HTA output to national reimbursement decisions, and it avoided what would certainly be a contentious debate by excluding issues of cost from European HTA from the outset. In the important question of uptake, however, DG SANTE opted for the maximally integrative but still potentially politically acceptable alternative, possibly to anchor subsequent negotiations or to leave a mark for the new, post-2019 commission.

Finally, an overview of key actors' positions revealed a potentially important role for domestic HTA and payer communities. If future research confirms that epistemic politics of nationally delimited HTA experts or interests of national payers (or, less intellectually interesting, lobbying of strong domestic medical device industry) were indeed at the origin of dissensus in key member states, this would be most closely reminiscent of the two-level games of (old) liberal intergovernmentalism (Moravcsik 1998), which sees domestic interests as key to member states' positions on EU issues. In this case, the relevant analytical category would perhaps not be dissensus but outright opposition at the domestic level, followed by bargaining at the EU level. This as well as other speculations explaining the behavior of the member states and other actors are impossible to verify without new interview or documentary data and are therefore beyond the possibilities of this article.

Conclusion

What does the case of health technology assessment tell us about the future of social Europe? First, integration is happening, even in such a high-salience and highly politicized area as the scope of publicly available health care. The loss of appetite for further integration may have stopped major events such as further enlargement of the EU but it does not prevent steps toward harmonization in social policy. The commission, in particular, remains a powerful actor, as remarked in other areas of social policy (Crespy and Menz 2015). In this sense, the neofunctionalist permissive dissensus is alive and kicking, at least to a point. Second, this harmonization is somewhat limited in its integrative goals—unifying the rules for how new drugs are evaluated is not inconsequential, but it is also not a revolution for European countries' welfare states. The boundaries repeatedly affirmed by the member states in the treaties are not being crossed. The new intergovernmentalist threat of a destructive dissensus fueled by "redirected" integration through the backdoor therefore seems limited. Third, harmonization is cloaked in technical proposals intelligible mostly to specialists

and sectoral insiders. These actors are able to decipher its potential consequences for national systems of social protection but seem to have little incentive to politicize the issue, thus potentially allowing for integrative policy solutions. The postfunctionalist dissensus, fueled by electoral dissensus, perhaps plays at most an indirectly constraining role. In other words, there can be low-salience integration even in high-salience areas. Fourth, harmonization is resisted by some member states, who use both substantive and procedural arguments focused on the merits and design of integrative proposals and procedural argumentation concerning subsidiarity and proportionality. The underlying reason for their resistance, sometimes overtly acknowledged, is a reticence to compromise on higher social policy standards some countries have—hardly a new topic in debates on social Europe. Whether this resistance extends to the technical aspects of supranational collaboration is debatable; for various reasons, harmonization has its proponents among European governments. As we have seen in the past (Greer 2006), however, harmonizing even deceptively specialized details may have unintended consequences for social policy.

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