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Author:

Katharina Böhm & Claudia Landwehr

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The Europeanization of Health Care Coverage Decisions: EU-Regulation, Policy Learning and Cooperation in Decision-Making

Böhm, Katharina/ Landwehr, Claudia

Department of Political Science Johannes Gutenberg-University

ABSTRACT

The paper presents two cases of Europeanization in health policy – an area that has so far been viewed as hardly affected by European integration. We show that even in the less likely case of coverage decision-making, some traces of Europeanization can be found. This is possible because the Commission has a strong interest in further integration in this field and all other relevant actors have motives to at least engage in cooperation. Our first case deals with the EU's transparency directive and shows that this has forced member states to establish formal decisionmaking procedures, but did not result in a harmonization of decision-making processes and institutions, which is why the Commission has fostered cooperation and networking. The second case looks at the Europeanization of health technology assessment, demonstrating how cooperation and policy learning take place and how the Commission has successfully promoted the emergence of a new policy field.

Introduction

Europeanization of health care is a complex issue. In principle and according to the treaty, the organization and delivery of public health care remains within the sole authority of the member states (Art. 168 No. 7 TFEU, formerly Art. 152 (5) TEC). At the same time, however, almost all 'inputs' needed to run a health care system (e.g. nurses, doctors, drugs, medical devices) enjoy market freedoms and are subject to various integration processes. This complexity has in several cases resulted in conflicts that had to be decided by the European Court of Justice, which through its jurisdiction gradually expanded EU-influence over certain fields of health policy (e.g. cross-border health care, competition of health insurance funds). By contrast, there are still various health policy areas where integration is marginal and the scope for Europeanization processes is limited. One example for an area in which integration has not yet taken place are health care coverage decisions. Which services and goods are provided by the public health care system varies widely between countries and depends on

various aspects such as available resources, the organization of the health care system, treatment habits and social values. For those reasons, the responsibility for the allocation of health care resources is fully left in the hands of the member states. Yet, even in this 'less likely' case (Martinsen 2012) some traces of Europeanization can be found, as our two case studies show.

Every year, thousands of new drugs and other medical technologies enter the market. Given the ever tighter public health budgets, decisions about which of these costly innovations are to be publicly financed become more and more important. These 'decisions about the basket of healthcare to which citizens are entitled and the mechanisms used to finance and deliver that healthcare (...) must be taken in the national context', as the Patients' Rights Directive puts straight (Directive 2011/24/EU). Hence, despite an EU directive that sets some requirements concerning the duration and transparency of those decisions, no formal provisions exist that tackle the issue on the European level. Accordingly, decisionmaking processes and decision outcomes vary widely between member states. Nevertheless, our first case study shows that cooperation and mutual learning are strongly fostered by the Commission. They do in some cases have an impact on the design of decision-making processes, although they do not result in a convergence of outcomes.

Our second case study describes the establishment of health technology assessment (HTA) at the European level. HTA is concerned with the evaluation of the effects and impact of health technologies and is commonly used as an evidence base for coverage decisions. Initiated by experts working in the field, European HTA cooperation began as a small EU-funded research project in the 1980s. With support of the Commission and due to the commitment of single experts and national HTA agencies, it has gradually developed into an institutionalized Europe-wide network. Although national HTA agencies now share resources and information, the resulting national reports remain divergent.

In the following section, we will first introduce the problem of health care coverage decision-making in more detail and discriminate coverage decisions from related regulative issues. We then provide reasons why further formal harmonization did not happen so far. We argue, however, that there also exist strong reasons and interests in favour of more integration that drive Europeanization processes in member states. The third section presents our first case study, which describes the diversity of coverage decision-making processes and the Commission's effort to foster cooperation and mutual learning between

member states. Section four portrays the Europeanization of HTA. In the final section, we sum up our findings and estimate chances of future Europeanization in this field.

Health Baskets and coverage decisions: a challenge for decision-makers

For normative reasons and because health care markets possess several characteristics (e.g. asymmetric information, supply-induced demand, uncertainty) that impede on efficient market allocation (see e.g. Arrow 1963; Folland, Goodman, and Stano 2010), all European societies have established public health care systems that organize the production and allocation of health care services and goods. Where allocation of scarce goods is not left to the market, the question of ‘who gets what, when and why’ has to be answered by political decision-makers. For long, governments have defined the scope of health care coverage only at a very general level, naming only broad service categories that are covered, and thus left the decision of ‘who gets what’ to medical doctors. In the last decades, however, demographic change has led to a growing demand for medical treatment, and technological innovation has produced not only high-cost services, but has also boosted patient expectations. Decisions about the specific content of publicly financed health baskets have thus become subject to more political regulation. The most common tool used to directly regulate the service coverage of public health care systems are positive and negative lists [1]. Positive lists name all services covered by the respective public health care system, while negative lists comprise items that are explicitly excluded from coverage. Most European countries apply such lists for pharmaceuticals, and some also have respective lists for procedures and medical aids. Coverage decisions are often tightly interrelated with other regulative aspects. One of those is the decision about the share of costs that are borne by the public health care system. The coverage of a particular treatment by the public system does not automatically imply that it is provided without charge. In most health care systems, patients pay a fixed share of the price or a prescription fee out of pocket, the level of which is decided upon independently from the coverage as such. Furthermore and in particular where drugs are concerned, coverage decisions are often interwoven with price regulations, as the price is one of the key variables influencing the outcome of coverage decisions. Many countries therefore settle the price to be paid for a drug in the same decision-making process they use to decide on its coverage [2]. In this article, however, we will neglect those

other regulative aspects and concentrate on the decisions about the in- or exclusion of medical goods and services into / from the public benefit basket. For several reasons, coverage decision-making is a challenging task. First, it requires highly specialized expert knowledge in different fields such as medicine, pharmacology, or economics. Second, coverage decisionmaking is characterized by a high level of uncertainty. In order to include innovations promptly, decisions must be taken at a time when only limited information is available. It is hard to foresee whether a specific treatment will be effective in practice, and possible gains (or losses) can thus only be estimated. Moreover, given the dynamic of medical innovation, countless new treatments and diagnostic technologies must be evaluated and decided on every year. Finally, coverage decisions are distributive decisions, meaning that the potential for political conflicts is high. Taken together, coverage decision-making is a complex and politically demanding task, which is why it has, at least partly, been delegated to specialized bodies in most European countries. The conjunction of regulatory and distributive aspects makes coverage decisions so difficult, but also so interesting to study from a perspective of Europeanization research. At a first, and probably even at a second glance, it seems that coverage decision-making is not a good case to study Europeanization processes [3]. The competencies to decide about the coverage of medical goods and services are completely under national authority, and the differences between member states are huge in almost all aspects relevant for coverage decision-making: the health care systems differ widely and so do the policy processes; member states are faced with distinct economic situations and thus can afford different levels of coverage; costs and prices of medical products and services are as diverse as are treatment guidelines and standards; and finally, social values and norms concerning for example the role of the state in health care or the emphasis on specific diseases or population groups vary strongly. Given all these differences, and due to the strong opposition of member states, further harmonization of coverage decision-making processes is apparently not within the realms of possibility. We argue, however, that this does not necessarily impede Europeanization processes. There are several strong interests on the national as well as on the European level that foster soft modes of integration and, at the same time, push Europeanization within member states.

Before presenting the arguments that militate in favour of a Europeanization of coverage decisions, it is necessary to briefly delineate the concept of Europeanization we

apply in this study, as the social science literature on this topic is huge and approaches are diverse (Featherstone 2003). Like all studies of Europeanization, we are interested in the impact of European integration on the domestic level (Radaelli and Pasquier 2008). European integration can in different ways have an impact on member states. Among them, the adaptation and implementation of EU law by member states has most intensely been studied, but is only of minor importance in our policy area. Of more relevance for coverage decision-making are other, more subtle processes like cooperation, learning, or networking. These “(h)orizontal effects” may be understood as the result of both increased competition and cooperation between countries and also of increased exchange of information and mutual learning simply by being part of an integrated Europe’ (Vink and Graziano 2008, 10). As the term ‘Europeanization’ is often misleadingly employed to describe or analyse the increasing similarity between policies among European countries, it is important to stress the difference between the concepts of Europeanization and convergence: While convergence concerns the similarity of outcomes, Europeanization has to do with the processes caused by European integration, which can result in both, convergent or divergent outcomes (Radaelli 2003).

Following from there, we consider Europeanization not as a top-down process but as a process that may be initiated by different forms of integration on multiple levels. In the case of coverage decision-making, we find hierarchical integration by means of legal regulation. It is supplemented by official forums of relevant stakeholders set up by the Commission, which aim at exchanging information and expertise. Thereby, cooperation does not always take place between all member countries but also occurs on a bilateral level (see below the example of a twinning project between France and Poland) or small groups of countries. In addition, there exist a number of informal cooperations and networks of national experts and other relevant actors (e.g. manufactures, sickness funds). These (formal and informal) forums and networks enable mutual learning, but also provide the arena for interest formation and joint actions as our second case study shows. Furthermore, being part of an integrated Europe can increase the pressure to justify national processes and decisions and thus drives national decision-makers into comparisons with their neighbours. Thus, the Federal Joint Committee – the German coverage decision-maker – for example, evaluated its new assessment process for innovative drugs by reference to decision processes in other European countries (Federal Joint Committee 2013).

From a European Community perspective, health care is an immense market that creates jobs and growth and that has become part of the European Single Market. In 2008, European countries imported health services and goods worth more than three billion Euros, mostly from other European countries (OECD 2010, 114). The differing decision-making procedures for technology appraisal and coverage of services, however, constitute barriers to trade and are thus in conflict with the common market. As we will show in our case studies below, the Commission therefore uses any opportunity to abolish these barriers and to alleviate intra-EU trade. The member states, however, are concerned about a loss of sovereignty. They are ultimately responsible for the well-being of their citizens, and thus hard to persuade to hand over the instruments necessary to achieve this goal. Furthermore, coverage-decisions can be an important tool of national pharmaceutical industrial policy (Permanand 2006).

Yet, provided that it does not come along with (too much) loss of power, there are good reasons for member states to foster Europeanization of coverage decision-making. As described above, coverage decisions need a lot of expert knowledge and they are time as well as resource intensive. Hence, member states could gain much from European cooperation. Another reason why member states may be open to further Europeanization is the possibility of blame avoidance. The decision about what to fund is always also a decision about what not to fund and results in a denial of treatment to certain patient groups. By allowing Europe a stronger role in decision-making, member state governments could pass the buck to Europe and thus avoid being held responsible for unpopular decisions.

Manufacturers of medical products also have a strong interest in the Europeanization of coverage decision-making. Standardized procedures would save them time and money. Among other things, the delay in market access due to time-consuming coverage decision-making has to be deducted from the duration of a patent, thus reducing the manufacturer's potential profit. Patients and doctors, too, demand timely access to innovative treatments, and can be enraged if a new technology is available in other member states, but not in their own country. At the same time, however, diversity in decision-making processes can also benefit manufacturers and patients when single countries are comparatively generous where funding for controversial technologies is concerned. Summing up, we argue that although there exist huge differences between national health care systems and member

states are not willing to lose sovereignty in this health policy area, there are good reasons and strong interests that support further integration as well as further Europeanization. And it is this ambiguity that makes coverage decisions an interesting and relevant subject for Europeanization studies.

The Europeanization of Coverage Decision-Making Processes

In order to restrict public health care spending, nearly all countries have introduced some form of price regulation and coverage restrictions. To ensure that those regulations do not hinder or distort intra-community trade, the Council has passed Directive 89/105/EEC, also known as the Transparency Directive, which came into force on 1 January 1990. This directive establishes requirements the member states have to fulfil in price regulation or when defining limitations on coverage for medical products. Concerning coverage decision-making, the directive commits the member countries to take and communicate decisions about the in- or exclusion of pharmaceuticals and other medicinal products in their positive or negative lists within 90 days (Art. 6 No. 1) [4]. Furthermore, the national authorities are obliged to base their decisions 'upon objective and verifiable criteria' and to provide a statement of reasons for the decision to the applicant (Art. 6 No. 2).

This directive has been in force for more than 20 years, but, as Table 1 shows, pharmaceutical coverage decision-making in Europe is more heterogeneous than ever. Table 1 compares selected characteristics of coverage decision-making processes for pharmaceuticals in 18 European countries [5]. The only feature shared by a majority of different countries is the existence of a positive list that registers all pharmaceuticals that are funded by the public system. The only exceptions are Germany, which employs a negative list of pharmaceuticals that are not reimbursed, and the special case of the UK, where primary care trusts (PCTs) at the local level are responsible for health care reimbursement.

Given the complexity and the potential for conflicts entailed in coverage decision-making, it is not surprising that the majority of European governments have at least partly delegated it to specialized bodies. Only in seven countries, reimbursement decisions are

Table 1. Pharmaceutical reimbursement decision-making in the EU

EU-member state	Reimb. lists	Who takes binding decision?	Advisory body	Members of advisory body ^j	Number of members	Transparency
Austria (At)	positive	Main Association of Austrian Security Institutions (<i>Hauptverband der österreichischen Sozialversicherungssträger</i>)	Pharmaceutical Evaluation Board (<i>Heilmittellevaluierungskommission</i>)	experts; representatives of social insurance, healthcare providers, labour union and employment association	20	only decisions public
Belgium (Be)	positive	Ministry of Social Affairs and Employment	Drug Reimbursement Commission of the National Institute for Health and Disability Insurance (<i>Commission de Remboursement des Médicaments</i>)	experts; without voting rights; representatives of social health insurance, healthcare providers, pharmaceutical industry, and ministries	28, 22 with voting rights	only preliminary reports and decisions public
Czech Republic (Cz)	positive	State Institute for Drug Control (<i>Státní ústav pro kontrolu léčiv – SUKL</i>)	-	bureaucrats of SUKL; representatives of social health insurance, manufacturers and experts are consulted	not specified	only decisions public

(Continued)

Table 1. (Continued)

EU-member state	Reimb. lists	Who takes binding decision?	Advisory body	Members of advisory body ⁱ	Number of members	Transparency
Denmark (Dk)	positive	Danish Medicines Agency (<i>Lægemiddelstyrelsen</i>)	Reimbursement Committee of the Danish Medicines Agency	medical experts	7	minutes and reports public
Finland (Fi)	positive	Pharmaceutical Price Board (<i>Läkemedelsprisnämnden</i>)	-	representatives of ministries and social health insurance; experts	7	only decisions public
France (Fr)	positive	Ministry of Health	Transparency Commission of the French National Authority for Health (<i>Commission de la Transparence</i>)	experts; without voting rights; representatives of public health administration, of health insurance funds, of pharmaceutical industry, experts; representatives of social health insurance and providers, patients without voting rights	28, 20 with voting rights	reports public
Germany (De)	negative	Federal Joint Committee	-	experts; representatives of social health insurance and providers, patients without voting rights	18, 13 with voting rights	meetings and reports public
Hungary (Hu)	positive	National Health Insurance Fund Administration (<i>Országos Egészségbiztosítási Pénztár OEP</i>)	Technology Appraisal Committee of OEP (<i>Technológia Értékelő Bizottság</i>)	representatives of OEP and of providers;	10, 8 with voting rights	only decisions public

(Continued)

Table 1. (Continued)

EU-member state	Reimb. lists	Who takes binding decision?	Recommendation body	Members of recommendation body	Number of members	Transparency
Ireland (Ir)	positive	Health Service Executive (HSE)	HSE Products Committee	HSE experts	7	only decisions minutes public
Italy (It)	positive	Board of the Italian Medicines Agency (<i>Agenzia Italiana del Farmaco - AIFA</i>)	AIFA Technical Scientific Committee (<i>Commissione Tecnico Scientifica</i>)	experts; AIFA president	19	minutes public
Luxembourg (Lu)	positive	Administration Council of the National Health Fund (<i>Conseil d'administration de la Caisse Nationale de Santé</i>)	Social Security Medical Inspectorate (<i>Contrôle Médicale de la Sécurité Sociale</i>)	bureaucrats	30	only decisions public
Netherlands (Nl)	positive	Ministry of Health Welfare and Sports	Committee for Pharmaceutical Help of the Netherland Healthcare Insurance Board (<i>Commissie Farmaceutische Hulp</i>) or Healthcare Insurance Board (<i>Raad van Bestuur</i>) ⁱⁱ	CFH: experts	21	reports public
Poland (Pl)	positive	Ministry of Health	Consultative Council of the Agency for Health Technology Assessment (<i>Rada Konsultacyjna of AOTM</i>)	experts; representative of doctors	10	reports public
Portugal (Pt)	positive	Ministry of Health	National Authority of Medicines and Health Products (<i>Autoridade Nacional do Medicamento e Produtos de Saúde INFARMED</i>)	INFARMED experts (bureaucrats)	n.n.	reports public
Slovakia (Sk)	positive	Ministry of Health	Drugs Categorization Commission (<i>Kategorizačná komisia pre lieky</i>)	representatives of ministry, social health insurance and professional public	11	minutes public

(Continued)

Table 1. (Continued)

EU-member state	Reimb. lists	Who takes binding decision?	Recommendation body	Members of recommendation body	Number of members	Transparency
Spain (Sp)	positive	Ministry of Health	-	bureaucrats	not specified	only decisions short minutes and reports public
Sweden (Sw)	positive	Pharmaceutical Benefits Board of the Dental and Pharmaceutical Benefits Agency (<i>Nämnden för läkemedelsförmåner</i>)	-	experts, patient representative	7	Meetings and reports public
England & Wales (EW)	iii	NICE. Technology Appraisal Committees ^{iv}	-	experts, patient, civil and industry representatives,	33	Meetings and reports public

Notes: 1ⁱ If there is no recommendation body, the information refers to the decision-making body.

2ⁱⁱ The Raad van Bestuur gives advice in the case of conditional reimbursement (bijlage 2), e.g. off-label use of drugs.

3 Technology appraisals are binding in the case of a positive recommendation only. If NICE gives no recommendation or recommends to not reimbursing a service, the PCTs that are responsible for health care provision, nevertheless are allowed to provide them.

4- The technology appraisal needs approval by the NICE Guidance Executive on behalf of the NICE Board.

taken immediately by the ministry, but even here, the ministries receive recommendations from expert bodies. Spain is the only country where the ministry of health has sole responsibility for the reimbursement process (Vogler, Espin, and Habl 2009). The variety of institutional solutions for advisory bodies is considerable, ranging from ministerial commissions (Slovakia) or state financed institutions (Poland) to more or less independent public health care institutions for which recommendations on reimbursement is only one of many tasks (e.g. Belgium, France). Experts play an important role in all of these advisory bodies, while stakeholders are included in fewer cases and typically with limited rights.

In countries where the ministry is not responsible for reimbursement decisions, decisions are either taken by more or less independent state bodies (Czech Republic, Denmark, Finland, Italy, Sweden), part of the public health administration (Hungary, Ireland, EW)⁶ or self-governance bodies (Austria, Germany). The state bodies do not only deal with coverage decisions but are in all cases also in charge of price negotiations and in some cases also responsible for the market authorization of pharmaceuticals (Cz, Dk, It). Here, too, experts play an important role in decisionmaking, and are complemented with stakeholders only in Finland [7]. In Ireland and the UK, the public health administration takes reimbursement decisions. While in Ireland the Health Service Executive (HSE) determines the inclusion of pharmaceuticals into one of the public schemes, coverage decisions in the UK are taken on the local level by the primary care trusts (PCTs). In order to improve equality in health service provision, the National Institute of Health and Clinical Excellence (NICE) was established in 1999 and charged with decisions on services and pharmaceuticals the PCTs have to fund. Decision-making processes in the UK and Ireland also differ with regard to their inclusiveness. While NICE involves many stakeholders, decisions in Ireland are taken and advised by HSE staff alone. Germany and Austria, by contrast, have a long history of self-governance and delegate reimbursement decision-making to respective bodies.

As its name indicates, the Transparency Directive aims to improve the transparency of coverage (and price) decision-making. While the requirements set by the directive are more or less fulfilled in all EU member countries, the processes differ greatly in the extent that meetings, proceedings and documents are made available to the public. While many countries publish only the eventual decisions, others make reports documenting reasons

and evidence on which decision-making is based available. Only few bodies publish the minutes of their meetings. In Germany and the UK, however, committee meetings are at least partly open to the public.

Given the variety of processes, it is hardly surprising that resulting decisions differ widely between the countries as well. We have analysed the coverage of ten controversial pharmaceuticals in European countries and have found a huge variation (Bořhm, Landwehr, and Steiner 2012). Our findings confirm earlier ones by Busse and colleagues (2011) who have studied the health care benefit baskets of nine EU-countries and concluded that the provision of pharmaceuticals is the area with the highest differentiation of coverage.

Summing up European reimbursement decision-making in the pharmaceutical sector, we can state that the one feature the separate national systems share is a formalised decision-making process. This is not much, but significantly more similarity than can be found in the area of medical services or medical devices, where many countries have not established a formalized decision-making process at all yet.

Historically, the Transparency Directive was the smallest common denominator that could be agreed upon. Originally, a more far reaching directive was intended, but could not be passed against the resistance of the member states that feared losing their sovereignty in the field of health care (Permanand 2006). The European Commission has never been satisfied with the marginal harmonization achieved by the Transparency Directive (e.g. European Commission. 2010, 2008a) and has therefore promoted further activities. Because further European regulation in this field seemed unobtainable, the Commission followed a softer strategy by fostering cooperation and networking of the relevant stakeholders. In 2006 it established the Pharmaceutical Forum [8], which brought together ministers, representatives of the European Parliament, the pharmaceutical industry, health care professionals, patients and insurance funds. This Forum selected pricing and reimbursement as one of its core themes and established a working group which analysed the pricing and reimbursement mechanisms applied by the member states and the resulting problems. In 2008, the Pharmaceutical Forum presented its conclusions and recommendations, demanding further cooperation and exchange of experiences and knowledge at EU level.

Moreover, the Commission has established a network bringing together important stakeholders in biannual meetings [9] and has funded the 'Pharmaceutical Pricing and Reimbursement Information Project' (PPRI) which gathered and published information on

decision-making processes in nearly all EU-countries [10]. Over time, this project has developed into a sustainable network of individuals and organizations operating in this field [11]. Finally, the Commission does not restrict its engagement to fostering cooperation and networking but is presently revising the Transparency Directive in order to adapt the Directive to the changing landscape of pricing and reimbursement regulation and to cover medical devices besides drugs.

A good example that reveals a European aspect on national coverage decision-making processes and that goes beyond cooperation on the European level is the twinning project ‘Transparency of the National Health System Drug Reimbursement Decisions’ between Poland and France. The European Commission had criticized the Polish decision-making process for its non-compliance with the Transparency Directive, especially for the long delay of decisions and missing transparency. In order to improve the decision-making process, a cooperation between responsible actors and experts from both countries was launched with the goals of defining objective and verifiable criteria for decisions, of providing clear information for applicants, of setting binding deadlines and of including expert opinions in the decision-making process. European experts conducted an analysis of the Polish system and provided advice on reforms. Based on these recommendations, the relevant actors in the Ministry of Health and the Polish HTA agency (Agencja Oceny Technologii Medycznych) developed reform measures in several workshops which took place between 2006 and 2008. Furthermore, Polish experts and persons working in the field were trained by European experts and could take part in internships and study trips. In the aftermath of the project, several transparency programs were launched in Poland. (Niz’ankowski and Wilk 2009; Zagorska et al. 2008)

1. Europeanizing the Evidence Base – The Case of EUnetHTA

As outlined above, direct regulation beyond the Transparency Directive is difficult. This is why the Commission’s strategy has been one of fostering cooperation and networking among the relevant stakeholders. Another example of this strategy is the Commission’s involvement in the field of health technology assessment (HTA). The importance of HTA in health and health care decision-making has been growing rapidly for two decades. In the majority of the European countries specialized HTA-agencies have been established and more and more health (care) decisions on all levels (patient, provider, regional, national,

European) are advised by HTAs. HTA can be defined as a 'multidisciplinary process that summarizes information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner (...)', the purpose of which 'is to inform the formulation of safe, effective health policies that are patient focused and seek to achieve best value' (EUnetHTA). One of the central fields in which HTAs are applied is decision-making on the inclusion of controversial medical services into public health baskets [12] Here, HTA is used to provide decision-makers with advice on the costs, effectiveness, budget impact, alternatives and other relevant measures of the technology in question. Given that HTA is a resource-intensive and time-consuming task, the hope is that cooperation and information sharing reduce costs and save time. Some even believe that using the same HTA as an evidence base in technology appraisal will lead to the same or at least similar outcomes. From early on, the European Commission identified the potentials of HTA and strategically promoted HTA at the European level. Its activity in the area dates back to the 1980s when its Committee on Health Services Research launched a programme on HTA which fostered scientific cooperation among European scholars and institutions working on HTA (Drummond 1987; Fracchia and Theofilatou 1993). In 1993, the European Commission funded EUR-ASSESS, the first of four consecutive HTA projects. Stakeholders from France, the Netherlands, Sweden, Switzerland and the UK had sought funding for an HTA programme at the European level, dealing with methodology, priority-setting, dissemination, and coverage. The most significant effect of this four-year project, however, has not been the resulting research outcome but the establishment of a European HTA network. The project had started with the members named above, but at the end of the programme nearly all member states of the EU participated (Banta, Kristensen, and Jonsson 2009). The next project, called HTAEUROPE, followed in 1997 with nearly the same participants. This time, the aim was to produce country reports describing HTA in the participating member countries (Banta and Wjia Oortwijn 2000). EUR-ASSESS as well as HTA-EUROPE recommended that a coordinating mechanism at the European level should be established (Banta, Kristensen, and Jonsson 2009). The Commission seized this suggestion in 1999 by funding a threeyear project that worked on the development of a mode of collaboration for health technology assessment (European Collaboration for Health Technology Assessment/ European Collaboration for Assessment of Health Interventions (ECHTA/ECAHI)). This project focused on the development of information exchange systems,

the support of joint assessments and the search for and dissemination of best practices in conducting assessments (ECHTA/ECAHI 2001).

Although no specific projects were running, HTA remained on the Commission's agenda in the following years. The High Level Group on Health Services and Medical Care, for example, had established a working group on HTA, and in one of its communications in 2004, the Commission highlighted the importance of HTA in evaluating technological innovations in order to avoid the expansion of public health budgets [13]. In this communication the European Commission complained about the fragmentation of HTA work in Europe and announced to establish a coordinating mechanism connecting existing projects, organisations and agencies. A next step was made in 2006 with the foundation of the European Network for Health Technology Assessment (EUnetHTA), [14] the fourth European HTA project. Again, this project was funded by the Commission, this time involving 50 partner organizations from 25 European countries [15]. The purpose of EUnetHTA was 'to create an effective and sustainable European network for HTA that would create common information frameworks for HTAs and promote the use of HTA in health care policy making in member states' (EUnetHTA 2009). EUnetHTA comprised eight work packages ranging from the support of HTA in member states with limited institutionalization of HTA to the development of a HTA core model as a basis for assessment sharing. Furthermore, a permanent secretariat and organizational structure were established to coordinate the network. As funding expired in 2008, EUnetHTA members provided interim funding for 2009 until EUnetHTA could be pursued as a joint action between the member states and the Commission in 2010. The joint action carries on with the work of EUnetHTA but also integrates the work of the 'Working Group on Relative Effectiveness' of the Pharmaceutical Forum described above. In a last step, EUnetHTA was institutionalized by Article 15 of the Patients' Rights Directive in 2011 [16]. The directive lays down the objectives of the network (support of cooperation, support of the provision and exchange of information on relative efficacy of health technologies, support the analysis of the nature and type of information, avoid duplication of assessments) and determines the conditions for the granting of Union aid [17].

In retrospect, EC engagement in HTA can be identified as a long but straight path towards HTA-Europeanization. HTA on the national and European level have developed almost simultaneously and interdependently. However, health care decision-making and

HTA in particular possess several characteristics that impede on the one-to-one transfer of methods and processes and that even make the sharing of information a difficult task, rendering convergence of outcomes unlikely. To begin with, HTA typically comprises only the first of several steps in the appraisal of new technologies: effectiveness analysis and economic evaluation (Røttingen, Gerhardus, and Velasco Garrido 2008), while assessment and appraisal mostly take place in separate institutions. Moreover, HTAs themselves differ widely between countries because countries apply distinct criteria in selecting which technology to assess, because data requirements and some country specific data vary, and because HTA-agencies around Europe use different analytical designs.

The most important factor for the differences to be found in HTA as well as in decision outcomes, however, are the criteria applied in decisions, which determine the results of assessments as well as the outcome of appraisals. Velasco Garrido and colleagues have studied coverage decision-making processes in nine European countries and have found a large number and considerable variety of criteria applied, such as appropriateness, budget restraints, cost-effectiveness, innovation or need. Those criteria are mostly defined by health care law and often remain highly abstract without specifying how to operationalize or weigh them against one another (Velasco Garrido et al. 2006). In order to be applicable in health technology assessments, however, criteria must be translated into methodological approaches. The criterion of cost-effectiveness, for example, only defines that the costs of an intervention are put into relation with its effects, permitting different methodological approaches. Decisions on which costs and effects to include in a model and on which methods to use in calculation affect the outcome of the assessment, hence turning a seemingly technical decision into a normative one. HTA is often perceived as the more 'technical' part of the decision-making process aiming to provide all necessary information for the final decision that has to weigh conflicting ethical and social values and to negotiate conflicting interests. Yet, in the area of HTA technical decisions cannot be separated from normative and distributive ones.

This also means that the outcome of an assessment is heavily influenced by the agency conducting the assessment, its work flow and methodological principles. Given this, the already existing variety of criteria is further increased by differences in the way they are weighted: decision-making is rarely guided by only one criterion, but typically, conflicting criteria must be considered. How are we to decide about the reimbursement of a treatment

for a minor complaint that is highly cost-effective but at the same time has a huge budget impact because a high number of people qualify as recipients? How about a last-chance treatment for terminally ill patients with uncertain effectiveness and a significant budget impact? And what if only one of the two treatments can be financed? In those cases the outcome of the appraisal will depend on the respective weight assigned to criteria like (cost-) effectiveness and need, which constitutes a normative decision that may differ from one person to another and one country to another. In appraisal processes, results will be strongly influenced by the stakeholders involved. As shown above, however, the composition of appraisal committees varies considerably across Europe. And we may assume that institutional characteristics like the independence of the appraisal committee, or the transparency of the process are also likely to influence the process and outcome.

Given this long list of context-specific characteristics and countless tiny setscrews of health technology assessments it becomes clear that the Europeanization of HTA is unlikely to result in convergent outcomes. Yet, the long and intensive cooperation of HTA-agencies in Europe has promoted HTA on the national as well as on the European level and has resulted in a tight network with a solid organizational basis.

2. Conclusion

Summing up the findings from our two case studies, we conclude that although health care coverage decision-making forms a 'less likely case' of Europeanization, different mechanisms of Europeanization can be observed in this policy field. With the Transparency Directive a traditional form of integration has led to a formalization of processes and stimulated the widespread use of positive lists. But as the member states resist further delegation of regulative competences, the Commission, which has a strong interest to further integrate this policy area, had to apply other instruments to promote integration. It fostered softer forms of Europeanization through nonbinding cooperation and networking of the relevant stakeholders. The example of the twinning project between Poland and France shows that this strategy works. In the second case discussed in this paper, the Europeanization of health technology assessment, formal European regulation has never existed. Nevertheless, with the aid of the European Commission as well as national HTA-agencies a strong European sphere has developed. Emanating from temporary cooperation projects, EUnetHTA is now a

permanent European HTA-institution that organizes cooperation and that tries to enhance harmonization.

The two case studies presented in this paper have once more revealed that Europeanization is a multilevel process that proceeds in various different forms. They have shown that where formal integration processes have their limits, alternative paths can lead to Europeanization, too, when they are pursued by strong interests. Looking ahead, there are even reasons to expect an increasing level of Europeanization in the future. First, the pressure on public health budgets is likely to swell as more and more expensive innovations flood the market rendering decisions to limit the content of public health baskets ever more important. Institutions at the national level, however, are overstrained by the sheer number of decisions required and thus will seek to further cooperate and share information and resources. We think it is not unlikely that EUnetHTA will become another European regulatory agency, given that HTA is by many actors perceived as the technical part of the decision-making process, which can be left to (European) experts. Second, the Europeanization of other health policy areas will have an impact on member states' coverage decisions. The European market approval of drugs, for example, can today lead to the situation that a drug is available, but not publicly reimbursed in a country, which, we think, will mobilize affected patient groups who will seek to bring decision-makers to reconsider their coverage decision. Furthermore, as patient mobility increases, patients will try to get treatments which are not reimbursed in their home country in other European health care systems where they are covered. Thus, what we described in this paper seems to be only the first step in the Europeanization of health care coverage decision-making.

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Notes

[1] Which medical services and goods are actually available in a public health care system depends on various factors such as, for example, the health care budget, the organization of service provision or the reimbursement scheme. We concentrate here on direct interventions to define the public health care benefit basket.

[2] There exist various different forms of price regulations (e.g. reference price systems, value based pricing). For an overview see Mrazek and Mossialos (2004).

[3] We owe the following counter arguments to an anonymous referee.

[4] If pricing and coverage decision is taken within one administrative procedure, the timeframe is extended up to 180 days (see Art. 6 No. 1 Transparency Directive).

[5] Table 1 presents data for European OECD-member countries, excluding Greece because of data problems.

[6] Hungary has a social insurance system that is strongly regulated by the state. The OEP which is in charge of reimbursement decisions is controlled by the state, which is why it has been classified here as public health administration.

[7] In the Czech Republic SUKL decision-making seems to be a more bureaucratic process where stakeholders as well as independent experts are consulted but not otherwise involved in decisionmaking.

[8] The Pharmaceutical Forum is a successor to the High Level Group on Innovation and Provision of Medicines, called in brief 'G-10 Initiative'. For a description of the EC's previous engagement in the area of pricing and reimbursement see Permanand (2006, 162ff.).

[9] Network of Competent Authorities for Pricing and Reimbursement of Pharmaceuticals.

[10] See: <http://ppri.oebig.at>.

[11] PPRI project leaders have also been heavily involved in advising the Working Group on Pricing of the Pharmaceutical Forum (Vogler, Espin, and Habl 2009).

[12] HTA is also used to inform the development of guidelines, inform treatment decisions on the individual level or to initiate public health strategies,. In general, HTA can be applied: first, to all interventions supplied by the health system (e.g. medical services, drugs, diagnostics, etc.), second, to interventions into the health care system (e.g. organization of service delivery, financing of the system, etc.) and third, to health interventions outside the health care system (e.g. environmental policies that aim at healthy living conditions)

(Velasco Garrido, Zentner, & Busse 2008). We will focus here on the former and restrict our analysis to HTA as a basis of reimbursement decisionmaking.

[13] Communication of the Commission: Follow-up to the high level reflection process on patient mobility and health care developments in the European Union, from 20 April 2004, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2004:0301:FIN:EN:PDF> (accessed 18 July 2011).

[14] See www.eunethta.eu.

[15] The partner organizations must be nominated by the national ministry of health. Besides the European partners, EUnetHTA involves five partners from Australia, Canada, Israel and the US as well as nine international organizations.

[16] Directive of the European Parliament and of the Council on the application of patients' rights in cross-border health care (2011/24/EU).

[17] The legal text is formulated in rather general terms and does not name EUnetHTA, but the description it gives of the designated network exactly fits EUnetHTA. In a communication preparing the Patients' Rights Directive, the Commission explicitly refers to EUnetHTA (European Commission 2008b).

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