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A regulatory governance perspective on health technology assessment (HTA) in France: The contextual mediation of common functional pressures☆

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ABSTRACT

The new regulatory governance perspective has introduced several insights to the study of health technology assessment (HTA): it has broadened the scope for the analysis of HTA; it has provided a more sophisticated account of national diversity and the potential for cross-border policy learning; and, it has dissolved the distinction between HTA assessment and appraisal processes. In this paper, we undertake a qualitative study of the French process for HTA with a view to introducing a fourth insight: that the emergence and continuing function of national agencies for HTA follows a broadly evolutionary pattern in which contextual factors play an important mediating role. We demonstrate that the French process for HTA is characterised by distinctive institutions, processes and evidential requirements. Consistent with the mediating role of this divergent policy context, we argue that even initiatives for the harmonisation of national approaches to HTA are likely to meet with divergent national policy responses.

1. Three insights of the regulatory governance perspective on HTA

At the intuitive level, the field of regulatory governance and the study of HTA seem well suited to one another. On the one hand, HTA is a means by which governments around the world have attempted to ensure comprehensive and equitable public access to the new and expensive range of medicines and treatments in the context of limited budgets for healthcare. And on the other, regulatory studies is a subset of governance scholarship concerned with the analysis of governmental steering activities, rather than the public provision and distribution of resources, that focuses on ways in which governments consolidate and organise individual policy sectors, and the techniques they use to incentivise the players within them [4]. Taking advantage of this appeal, a new generation of scholars has opened a regulatory governance perspective on HTA to produce some valuable insights into the study of HTA in Europe [1–3].

In the first place, regulatory scholars have broadened the scope for the analysis of HTA, demonstrating that HTA does not take place within single isolated institutions that apply self-selected methods and process, but occurs across a broader decision-making network that responds

☆ The introductory sections of the paper draw upon work in other papers published by this research group [1–3]. This is due to the fact that we have conducted this research together and have developed and applied the theoretical framework for analysis jointly.

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to specific cultural and institutional environments. Considering the use of the Efficiency Frontier under the German approach to HTA, Klingler et al. show that efforts to improve the conduct of HTA based on comparative analyses that describe different HTA methods, determine 'what works best' and formulate best practice guidelines for ubiquitous application are misguided. Policy makers, they suggest, are unlikely to introduce measures for the improvement of HTA that run counter to the existing cultural and historical preferences. Accordingly, the study of HTA must take place under a significantly broadened conceptualisation of HTA, and involve an analytical framework capable of capturing the relevant cultural, historical and institutional determinants [1].

Secondly, regulatory scholars have also introduced a more sophisticated take on national diversity and policy learning with respect to HTA methods and processes. The field of regulatory governance reaches across the wide variety of policy sectors, from banking and finance, shipping and aviation, and gambling and healthcare, to name but a few. Considering the role of the County Councils in the delivery of Swedish healthcare, Shah et al. draw on the insights of regulatory governance theory to suggest that HTA scholars should expect to encounter diversity with regard to national methods and processes. Globalisation, they suggest, touches sectors, markets and regulatory regimes to different degrees. In banking and finance, for example, both markets and regulations are global. In terms of other sectors, like gambling and healthcare, however, both markets and regulations are national. In the case of health technologies, regulations are subject to globalisation, but markets are not [5,6]. Today, individual nation states are among the largest buyers in pharmaceutical markets. Accordingly, there is more scope for variation in national regulatory arrangements for health technologies than in arrangements for sectors like banking, finance and aviation, which require unified regulatory regimes towards the construction of which nation states, private enterprises and third sector organisations necessarily collaborate [2,7]. And certainly, in terms of institutions, processes and evidential requirements for HTA, national states exhibit significant differences and divergences, which limits opportunities for policy learning across states. However, this is not to imply the impossibility of policy learning, rather to suggest that complex national dynamics and traditional regulatory-governance structures have a bearing on the types of policy lessons that analysts might reasonably expect to extract and apply. Indeed, by using the right cases-studies, analysts may even increase the potential for policy learning and transference. For example, in the case of Sweden, some national environments, notably Spain which has a similarly structured health care system, may be more relevant to reflecting on and potentially improving the Swedish approach than other national models [2].

Thirdly, regulatory governance scholars have problematised the notion of a distinction between HTA assessment and appraisal processes [3]. For example, some analysts suggest that HTA consists of a formal assessment process, which produces knowledge about new healthcare technologies, and a more context-specific appraisal process, which translates the analysis into policy advice and decision-making [8]. Under the distinction, HTA assessment processes are considered broadly transferable across national contexts. On this basis, some, and notably English analysts, have suggested that organisations like the National Institute for Health and Care Excellence (NICE) in the UK set an international 'benchmark' for the use of evidence in HTA, which derives from the practice of evidence based medicine and even the European Enlightenment [9]. However, the regulatory governance perspective is unconvinced by these claims, affirming that appraisal and assessment processes are mutually constitutive, or that the policy making context in which HTA is conducted holds consequences for the way that evidence is used in the HTA process. For regulatory scholars, NICE's so called 'assessment process' has little to do, as English commentators are wont to suggest, with evidence based medicine and the European enlightenment, and much more do with the fact that NICE assessments must drive a health system that involves universal and free access to healthcare, and in which the profits and prices of pharmaceuticals are regulated by an initial agreement between industry and government. Thus, regulator scholars claim that NICE's rigorous, and arguably expensive, application of economic analyses, the use of Quality Adjusted Live Years (QALYs) as a benefit measure and a funding threshold, derive from the necessity to make comparisons of the cost-effectiveness of medicines across individual disease areas—for the purpose of establishing whether or not public money is more effectively invested in the latest cancer treatment or the latest diabetes treatment—or in other words, to ration healthcare [9]. In such cases, the regulatory governance perspective asserts the internal coherence of national approaches to HTA, denying that one can set a so-called 'benchmark' for any other system. Indeed, the desirability of policy goals in particular contexts necessarily conditions any potential benchmarking exercises. In other words, NICE could set a benchmark for HTA only insofar as the goal of rationing healthcare became desirable in other national contexts. However, even in that situation NICE would only constitute an adequate benchmark where the same values (utility maximisation) underlay the rationing process.

2. The contextual mediation of common functional pressures

The purpose of this paper is to articulate a fourth insight of the regulatory governance frame to the study of HTA. At the European level, the emergence of varied national approaches to the conduct of HTA has produced calls for the harmonisation of methods and processes across the EU. And today, there remains significant interest in the exchange of information about HTA process and potential initiatives for cross-border collaboration in the name of reducing expenditure and the duplication of HTA work programmes [10,11]. At the industry level, there is also much support from major pharmaceutical companies for a harmonisation of HTA methods for the purpose of producing nationally transferable results [12]. European policy analysts likewise support the establishment of a European drug pricing and reimbursement agency similar to the European