

Propositions

Governance of European Cooperation Processes in Health Technology Assessment

Networking, paving the way to convergence of practices?

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1. Effectiveness of soft governance as a tool to reach convergence of practices in HTA cooperation depends on the manner in which specific soft governance instruments are implemented rather than supposed inherent weaknesses of soft governance modes themselves and is favoured when implemented through governance networks.
2. Soft governance bears the potential to provide the flexibility and gradualism needed in EU integration policies of sensitive policy areas, such as HTA, and its place and functionality in the EU governance modes should therefore be reconsidered as a real alternative to classic integration modes permitting convergence of policies whilst preserving national interests.
3. Soft governance can impact the application of the subsidiarity principle in health policy and HTA as it bears the potential to strengthen EU coordinated cooperation processes leading to convergence of policies whereby progressively objectives of a proposed action, by reason of scale and effect, could be better achieved by the Community than by the Member States.
4. Harmonisation of HTA processes in the EU cannot be reached by soft governance modes alone requiring additionally a European legislative framework based on flexible cooperation structures, organised in clusters of similar national health systems.
5. Active participation of domestic (hard) policymakers in cooperation processes seeking to establish a sustainable European HTA cooperation mechanism is a pre-requisite for effective uptake of joint work and adherence to new EU legislative frameworks seeking convergence of practices.
6. The membership structure of HTA governance networks impacts the effectiveness of soft governance in establishing a sustainable European cooperation structure through social interaction amongst senior-level representatives of HTA bodies, stakeholder groups and domestic and European policy-makers.
7. Convergence of European and national regulatory processes is facilitated by the presence of a shadow of hierarchy herewith enhancing the effectiveness of soft governance in establishing sustainable cooperation mechanisms.
8. An important factor favouring convergence and harmonisation of HTA processes in Europe and overcoming national disparities in HTA methodologies is the cooperation of academic institutions as these, to date, predominantly transmit domestic HTA values and understanding amongst HTA doers.
9. The present distribution of competences in the European Union regarding serious cross-border threats to health, fails to effectively address crisis situations and calls for a renewed transparent legislative framework whereby Member States shift part of their competences to the Union level.
10. To ensure regulatory processes are not disrupted from serving the public good, social and ethical considerations should regain an important position in evaluation processes of medical devices, pharmaceuticals and innovative approaches in health care, often driven predominantly by economic considerations and influenced by powerful industry lobbying activities, not necessarily tuned into public and patients' interests.
11. Analysing soft governance through the prism of *network analysis* provides innovative insights as to the impact and effectiveness of soft governance instruments on policy making processes.