

# LEGAL ASPECTS IN HTA

## A structured guidance to identify legal issues of health technologies and their relevance in HTA

### Purpose of the legal guidance

- Provide a structured question-based framework to allow identification of 9 legal core aspects relevant for the assessment of complex technologies
- Indicate the importance of solving identified legal problems depending on the respective decision level
- Indicate relations with other (also non-legal) aspects in HTA
- Indicate relevant legal sources to start with for in-depth-analyses



The guidance for assessing effective-ness, economic aspects, ethical aspects, socio-cultural aspects and legal aspects in complex technologies can be downloaded from: <http://www.integrate-hta.eu/downloads/>

### Localisation of Legal Aspects in HTA

Decision level	Legal issues	Overlapping HTA aspects
Micro and Meso Level	1. Informed Consent	Ethical and Socio-Cultural Issues
	2. Alternative forms of Consent	
	3. Privacy and Data Protection	
Meso and Macro Level	4. Authorisation of Medical Devices	Clinical Issues and (possibly) Ethical Issues
	5. Authorisation of Medicinal Products	
	6. Clinical Trials	
	7. Intellectual Property	Legal and Ethical Issues
	8. Reimbursement in Public Health Care Systems	All parts of the HTA
	9. Special Medical Fields	Ethical and Socio-Cultural Issues

### Steps of the legal guidance regarding each core aspect:

- Question to allow identification of relevance of the legal aspect in question
- Legal explanation of the aspect and examples for further clarification
- Legal sources relevant for the aspect
- Relations of the aspect to other parts of the HTA
- Reference on relevant decision level and necessity of professional legal advice for further assessment

### Added value the legal guidance

- Determining relevance of legal aspects dependent on different levels of decision-making, this guidance avoids unnecessary (for example multiple) assessments of aspects of minor importance for the specific HTA
- The guidance can be applied as part of the INTEGRATE-HTA model (see the guidance on integrated assessment) and as a standalone.

