EUROPEAN ASSOCIATION of HEALTH LAW

UMIT
the health & life sciences university

Health Technology Assessment (HTA) and Access Policies

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FONDAZIONE PER LA RICERCA FARMACOLOGICA GIANNI BENZI ONLUS

XII FORESIGHT TRAINING COURSE
INNOVATIVE MEDICINE AND RESEARCH: ETHICAL, LEGAL AND REGULATORY ISSUES
HOTEL DIEU

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Toulouse, France

Content

1. Background
2. Case Study
3. Access Policies and Decision Support
4. HTA
5. Discussion

Oviedo Convention

Article 3 – Equitable access to health care

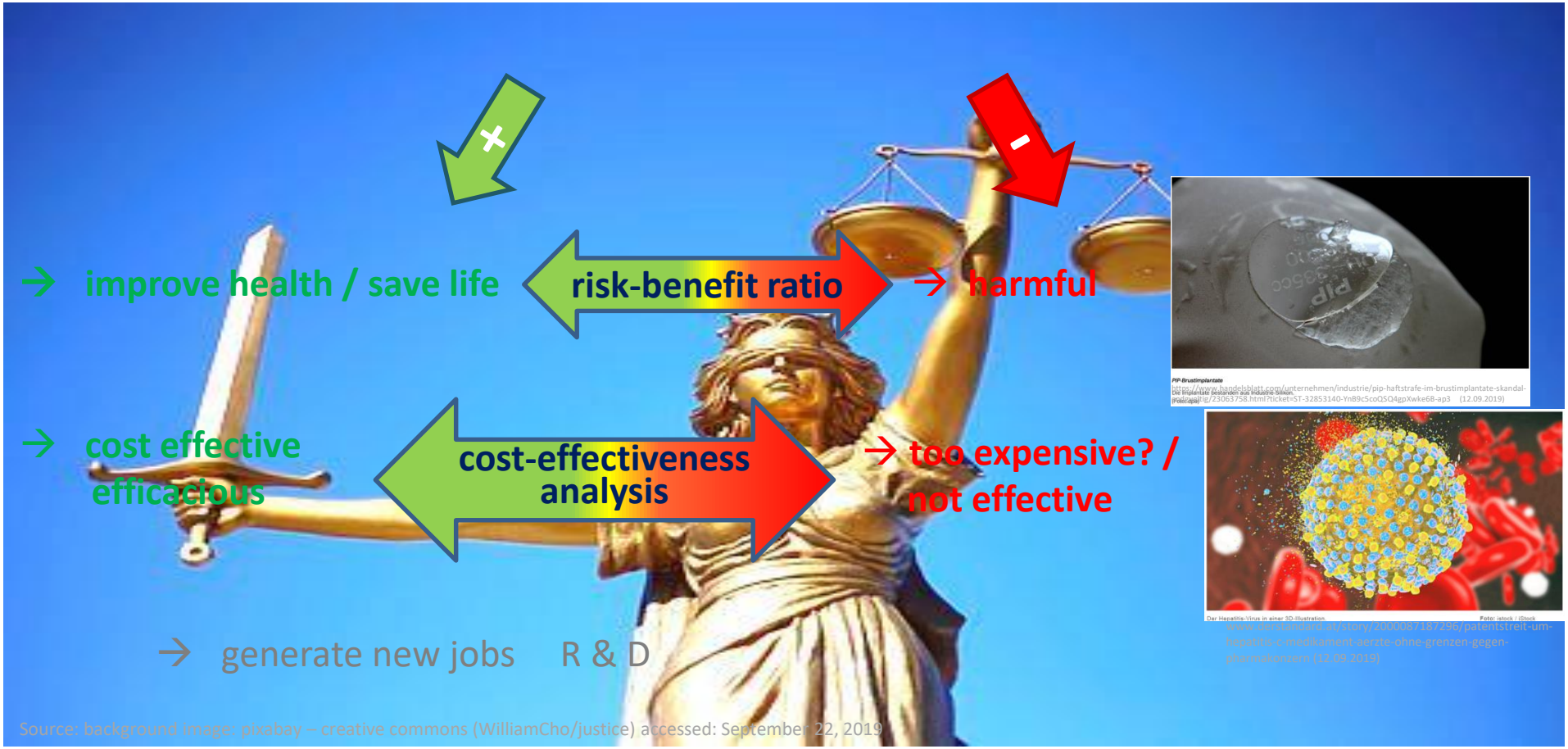
Parties, taking into account health needs and available resources, shall take appropriate measures with a view to providing, within their jurisdiction, **equitable access to health care of appropriate quality**.

European Treaty Series - No. 164

Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine * Oviedo, 4.IV.1997

Background

New Health Technologies



https://www.handelsblatt.com/unternehmen/industrie/pip-haftstrafe-im-brustimplantate-skandal-prozess-ig/23063758.html?ticket=ST-32853140-YnB9c5coQSQ4gpXwke6B-ap3 (12.09.2019)

https://www.stern.de/gesundheit/story/A000087167456/patentstreit-um-hepatitis-c-medikament-aerzte-ohne-grenzen-gegen-pharmakonzern (12.09.2019)

Source: background image: pixabay – creative commons (WilliamCho/justice) accessed: September 22, 2019

Case Study

Sovaldi © Gilead (Sofosbuvir)

How much money per patient/year would you be willing to spend?

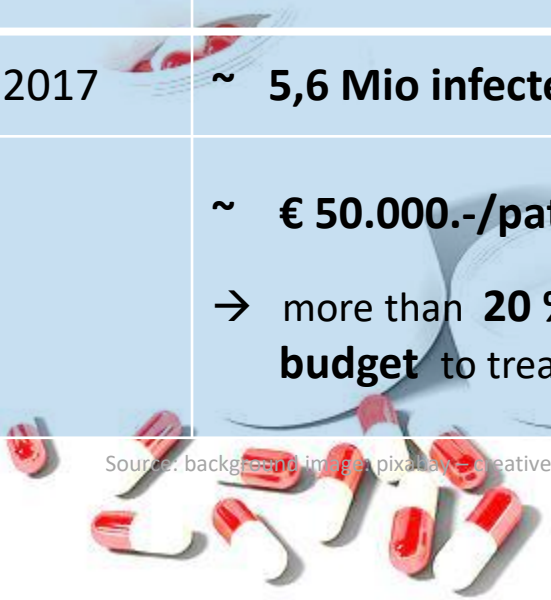
Which factors would influence your decision making?

Source: background image: pixabay – creative commons (Vacho/medikamente), accessed: September 22, 2019

Case Study

Sovaldi © Gilead (Sofosbuvir)

Some more facts …	
Incidence (EU and EEA) in 2017	~ **5,6 Mio infected people** (RKI (2018))
Costs (EU)	~ **€ 50.000.-/patient/treatment** (LBI (2014)) → more than **20 %** of a **yearly medicines-budget** to treat all patients in one MS (LBI (2016))



Source: background image pixabay (CC creative commons (Vacho/medikamente), accessed: September 22, 2019

How much is this specific medicine worth?
How much can it cost in publicly/on the basis of solidarity financed health systems?

Access Policies

Does it work?

Is it worth being covered (at what price)?

Innovativeness and Safety		Equal and Affordable Access to new Health Technology		
R&D Research and Development	MA Marketing authorization	Decision Support Before P&R Decision	P&R Decision	Market monitoring after P&R Decision
		Horizon Scanning	Procurement procedures	Competition Law
		HTA	Tendering	Pharmacovigilance
			Market Entry Agreements	

New Health Technology

Table 1: Tools and Regulatory Framework to ensure equal and affordable access to new health technology (own compilation, based on: Vogler S, Paris V, Panteli D (2018), Ensuring access to medicines: How to redesign pricing, reimbursement and procurement? Policy Brief 30, World Health Organization 2018 (acting as the host organization for, and secretariat of, the European Observatory on Health Systems and Policies).

Decision Support

independent

Decision Tools for **Health Policy Makers**

- Horizon Scanning
- HTA
- Procurement Procedures
- Market Entry Agreements (MEA)
- Tendering

fragmented

- Regional/local level (political)
- Regional/local level (institutional)
- National level (political)

Administrative Authorities and **Courts**

e.g. Competition or health authorities

HTA - Definition

*"HTA is a method of **evidence synthesis** that considers evidence regarding **clinical effectiveness**, **safety**, **cost-effectiveness** and, when broadly applied, includes **social**, **ethical** and **legal aspects** of the use of health technologies."*

HTA aims at answering the following 3 questions:

1. *"Whether a new health technology **does work** (Effectiveness)?"*
2. *"Whether the new health technology is **worth it** (Economic Value)?"*
3. *"Whether the new health technology is **worth being implemented** or covered by the public system' (coverage by public system)?"*

Bryan R. Luce et al (2010) pp 271-272, p 271

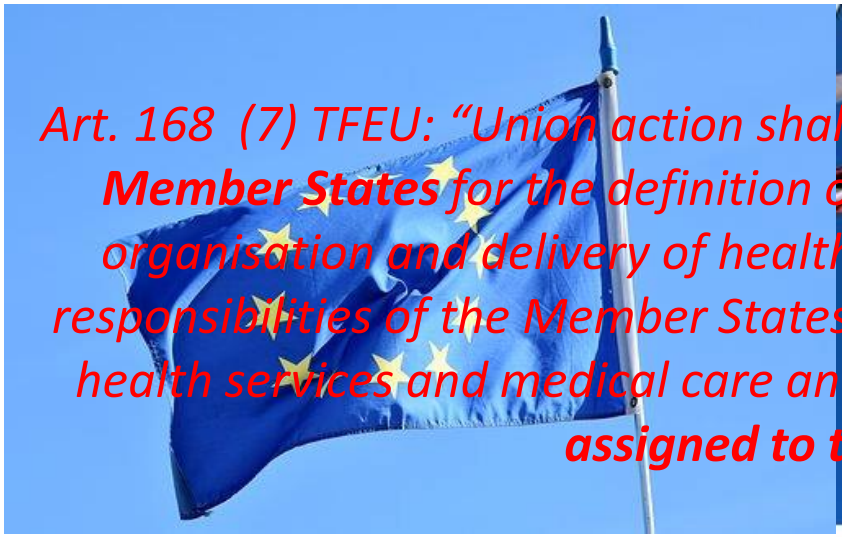
HTA (so far) does **not** aim at **recommending** a **price** for a **new technology,** thereby considering **ability to pay/economic situation of different countries (in the sense of a 'differential pricing'** see Vogler et al (2015) **/fair price building).**

European Level - ?

Competence ?

EU

Member States



*Art. 168 (7) TFEU: "Union action shall respect the responsibilities of the **Member States** for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the **allocation of the resources assigned to them** […]."*

Source: Pixabay – free images

HTA

Competence ?

EU **Member States**

Source: Pixabay – free images

Joint HTA strategy - Legal Basis

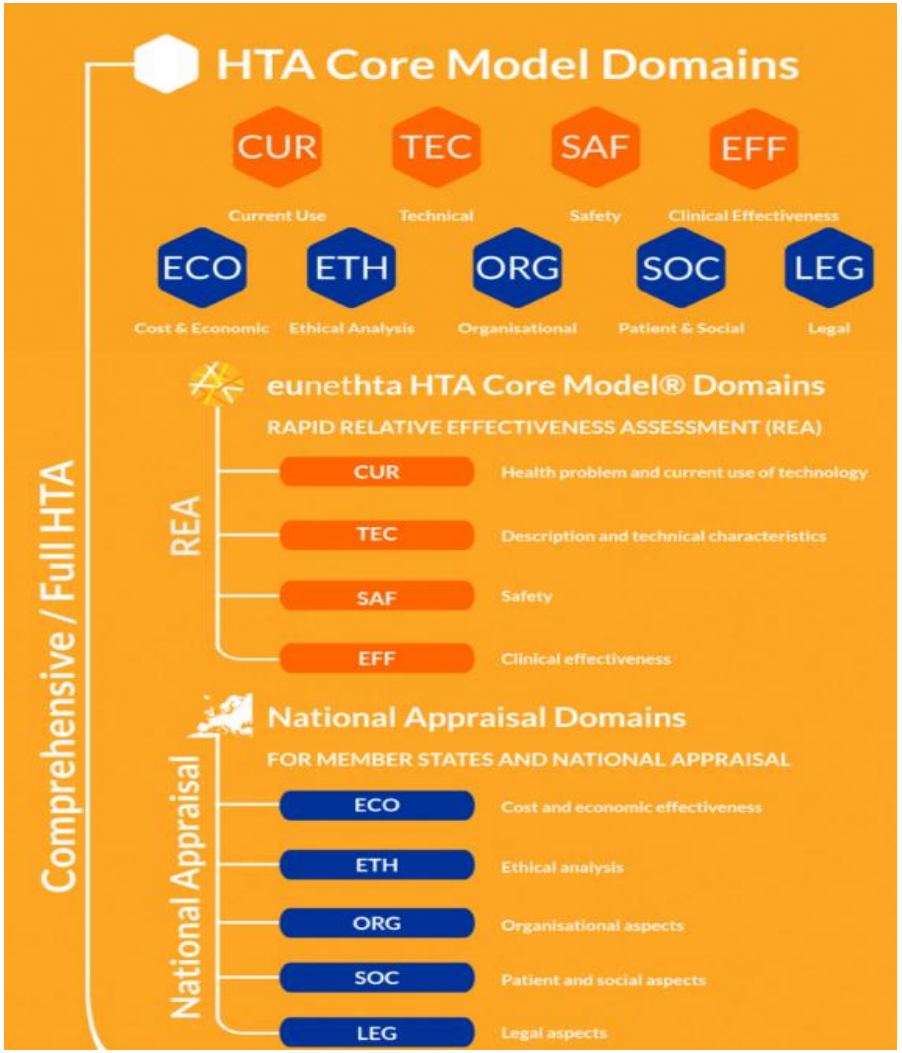
- **Directive 2011/24/EU** on the application of **patients' rights in cross-border healthcare**:

  Art. 15 : "***functioning network of national HTA-agencies*** *and bodies",* thereby *"assuring the* ***exchange of scientific information***." → **EUnetHTA**

- **European Commission**: **Proposal for a Regulation** of the European Parliament and the Council on **health technology assessment** and amending Directive 2011/24/EU COM(2018) 51 final (31.1.2018) – based on Art. 114 TFEU (**Internal Market)**

- Amended text by the **European Parliament** (first reading) (14.2.2019) – based on Articles 114 and 168(4) TFEU **(Internal Market** and **Public Health)**
  - **joint clinical assessments** by a **coordination group / sub-groups** for:
    → medicinal products,
    → other medicinal products not subject to the authorisation procedure ,
    → specific medical devices (classified as class IIb and III)
    → specific in vitro diagnostic medical devices (classified as class D)

Reference to EUnetHTA Core Model



Source: https://www.eunethta.eu/hta-core-model/ (accessed: September 23, 2019)

Case Study

Sovaldi © Gilead (Sofosbuvir)

How much is a specific medicine worth?

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Source: background image: pixabay – creative commons (Vacho/medikamente), accessed: September 22, 2019

→ For **companies**: **duty to disclose financing** and **costs**, **if public funding** for research and development has been received → this information could be used for pricing recommendations in Joint HTA

→ For **decision makers**: **duty to disclose conditions of MEA** (also: Risk-Sharing-Agreements), etc..

Critical Appraisal of Legal Basis

Proposal of a Regulation on HTA –
as amended by the European Parliament (first reading) (14 February 2019)

→ **Transparency/incomplete information**: no **duties for companies** to provide insights about financing and costs for research and development (if public funding has been involved) / no **duties for Member States** to provide insights of MEA, etc. regarding existing/new products.

→ **Financing** mechanism: work of coordination Group (and sub-groups) shall be financed by Union – what about the financing of the scientific input necessary for a high quality of work?

→ Still very much based on **voluntary cooperation** (no HTA-agency)

Obstacles for joint HTA in Europe

Europe is divers …

- **No EU HTA-Agency** - different competencies/procedures/methodologies of HTA agencies in Member States
- **Intransparent assessments** (in some countries assessments are even confidential), etc.
- **Independence of HTA-bodies: different standards** re conflict of interest
- **Missing data for assessments**
- **Fragmentation of national health systems** (high variety of decision making bodies due to federal systems)
- Assurance of **timely delivery of joint HTA**, ….

(see also European Commission (2017)2455149 - 15/05/2017)

Discussion

- **Fair Pricing**:
  Which (further) information is needed for fair pricing mechanisms?
  How can access to this information be provided?
  Should pricing recommendations be included in HTA reports?

- **Health Market**:
  Is the health market really to be treated like a regular other 'internal market'?

- **Patent Law**:
  Patents in combination with other property rights and intransparent decisions in Member States lead to strong negotiating positions of companies and to high priced technologies.
  Could/should adjustments in patent law contribute to more sustainable health systems and **equitable access to health care of appropriate quality**?
  (see also: Wildt C in Nowotny M (2018)).

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