Medical technologies and financial sustainability – do we know what we need to know? A systems‘ view

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NO!

But how do we get there?

Background

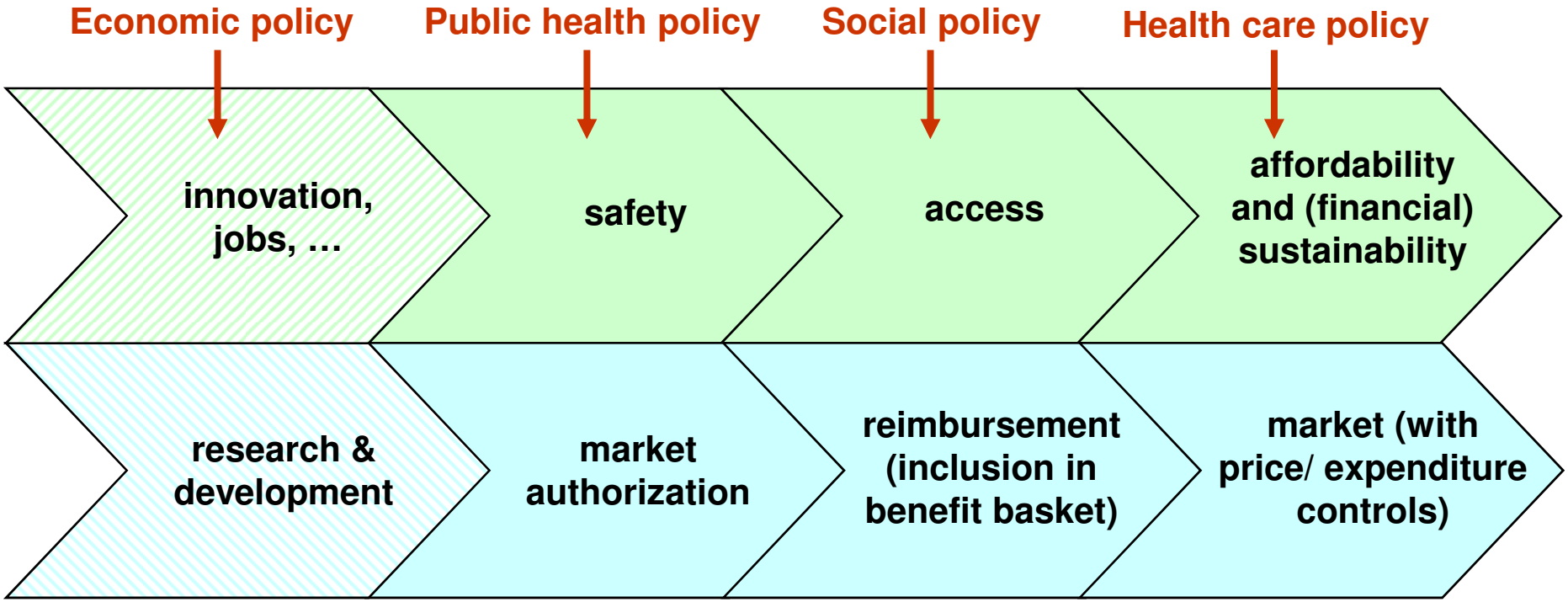
Medical technology industry relevant in terms of employment and turnover but not very visible in policy and academia

-> plausible industry claim of innovativeness (and therefore “value” to society)

-> but scarcity of European data on medical and economic value of medical technologies

-> might lead to application of financing, evaluation and regulatory instruments derived from pharmaceuticals

Different policy objectives …



way of medical devices into and through the health care system

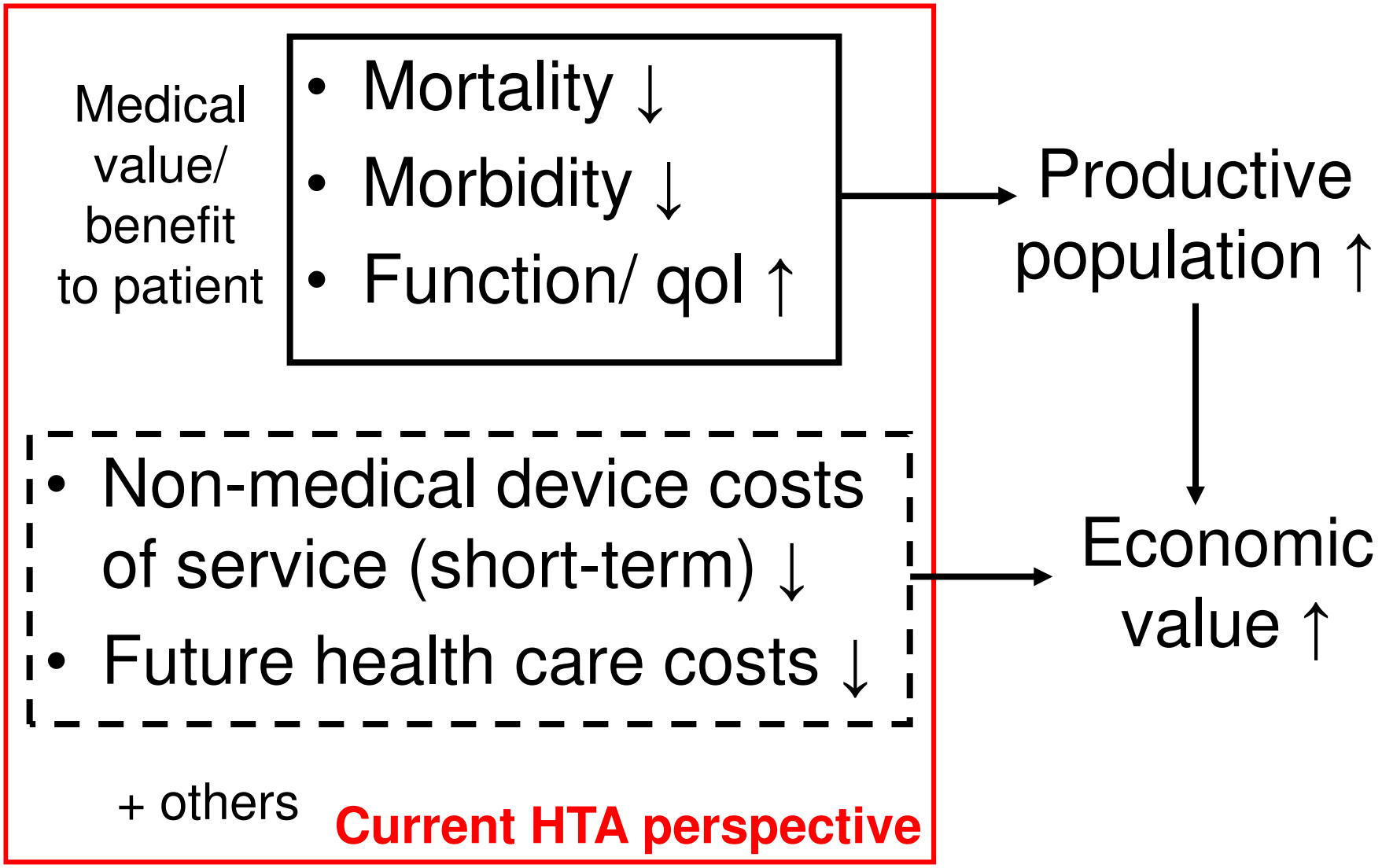
Addressing gaps and challenges – Research on Medical Technology

- Aims and objectives
  - Conduct high level research on the economic and health implications of medical technologies, in particular, medical devices
  - Bridge the gap between medical technology industry, academia and health policy
  - Provide decision-makers with robust evidence on the social & economic value of medical technology
  - Contribute to the debate on access, availability, diffusion and optimal use of medical technologies in Europe

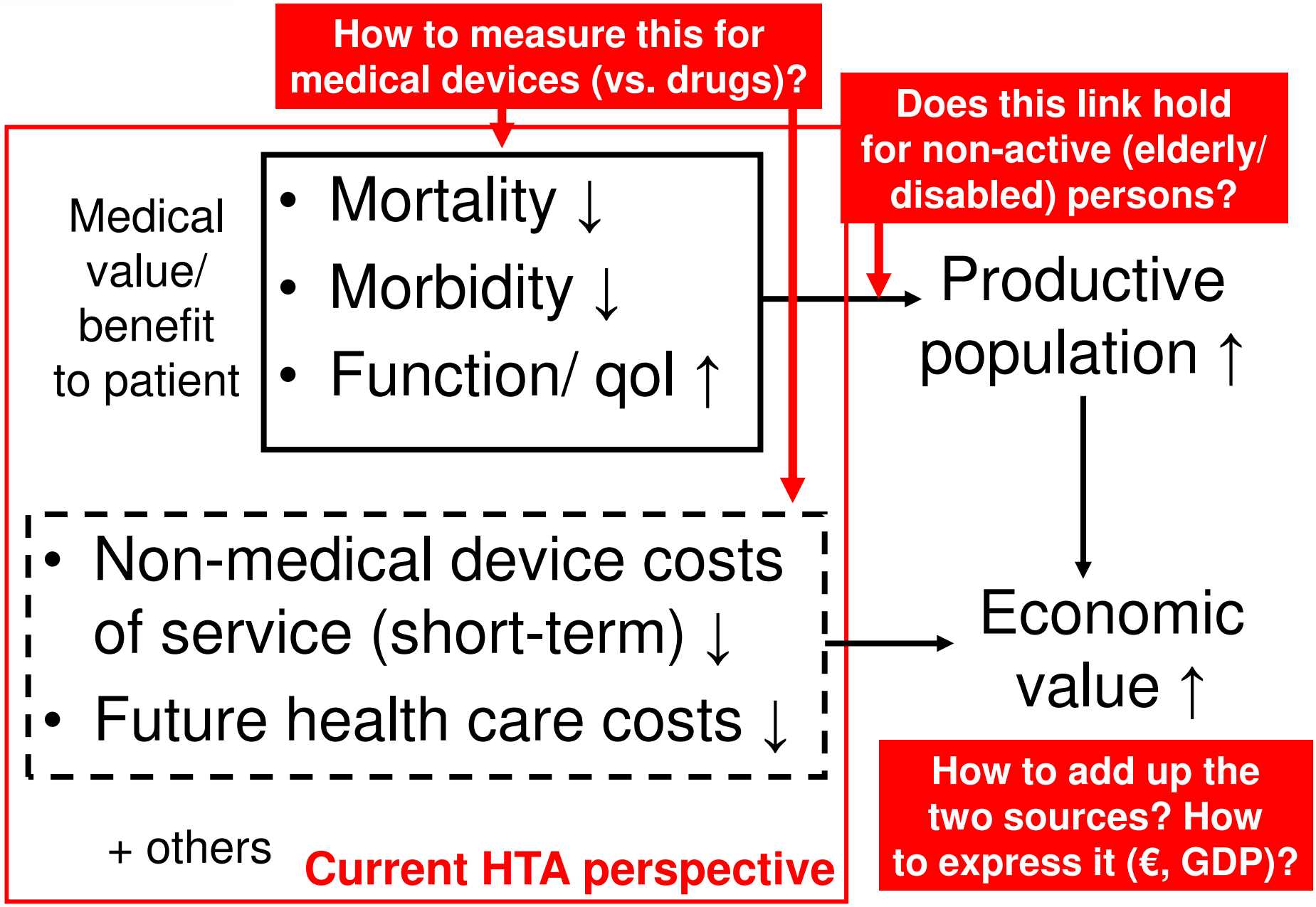
Addressing gaps and challenges – The research agenda

- Bringing health technologies onto academic *(-> publications)* and policy agendas
- Understanding market access, coverage, financing, utilisation and actual/ potential benefit of selected technologies
- Comparing regulatory policies across countries and technologies in respect to current (and future) economic, health and social policy objectives and overall „economic value“
- Identifying „good“ and „bad“ regulatory policies in order to help shaping future policy

Conceptualizing „economic value“



Research questions



Medical technologies classification – causing more confusion than clarity?

01	Active implantable technology	
02	Anaesthetic and respiratory technologies	
03	Dental technologies	
04	Electromechanical medical technologies	X-ray, CT scanner …
05	Hospital hardware	
06	In-vitro diagnostic technology	
07	Nonactive implantable technologies	
08	Ophtalmic and optical technologies	Eye glasses, contact lenses; ophtalmoscope
09	Reusable instruments	
10	Single-use technology	
11	Technical aids for disabled people	
12	Diagnostic and therapeutic radiation techn.	

A structure of medical device technologies based on financing and usage in health care system

Category 0 "Supporting technologies to Category I to III"

Reusable instruments, single use technology etc.: syringes, X-ray films, ….
Technology = part of Cat. I to III, not reimbursed separately

Category I "medical aids"

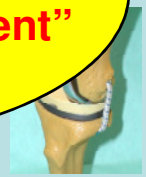
products which are prescribed and given to an individual patient

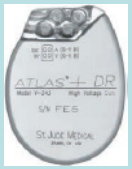
In-between category I-II: "medical aids with large service component"
(e.g. exo-prostheses)

Example technologies
- incontinence pads
- wheel chairy
- pregnancy test

Category II "artificial body parts"

medical devices which stay at or in the patient (e.g. knee endoprostheses, stents): only one component of a broader "service package" to implant or adapt the ware) product" to the al patient





- knee (endo-)prosthesis
- Implanable Cardio-Defibrillator
- coronary stents

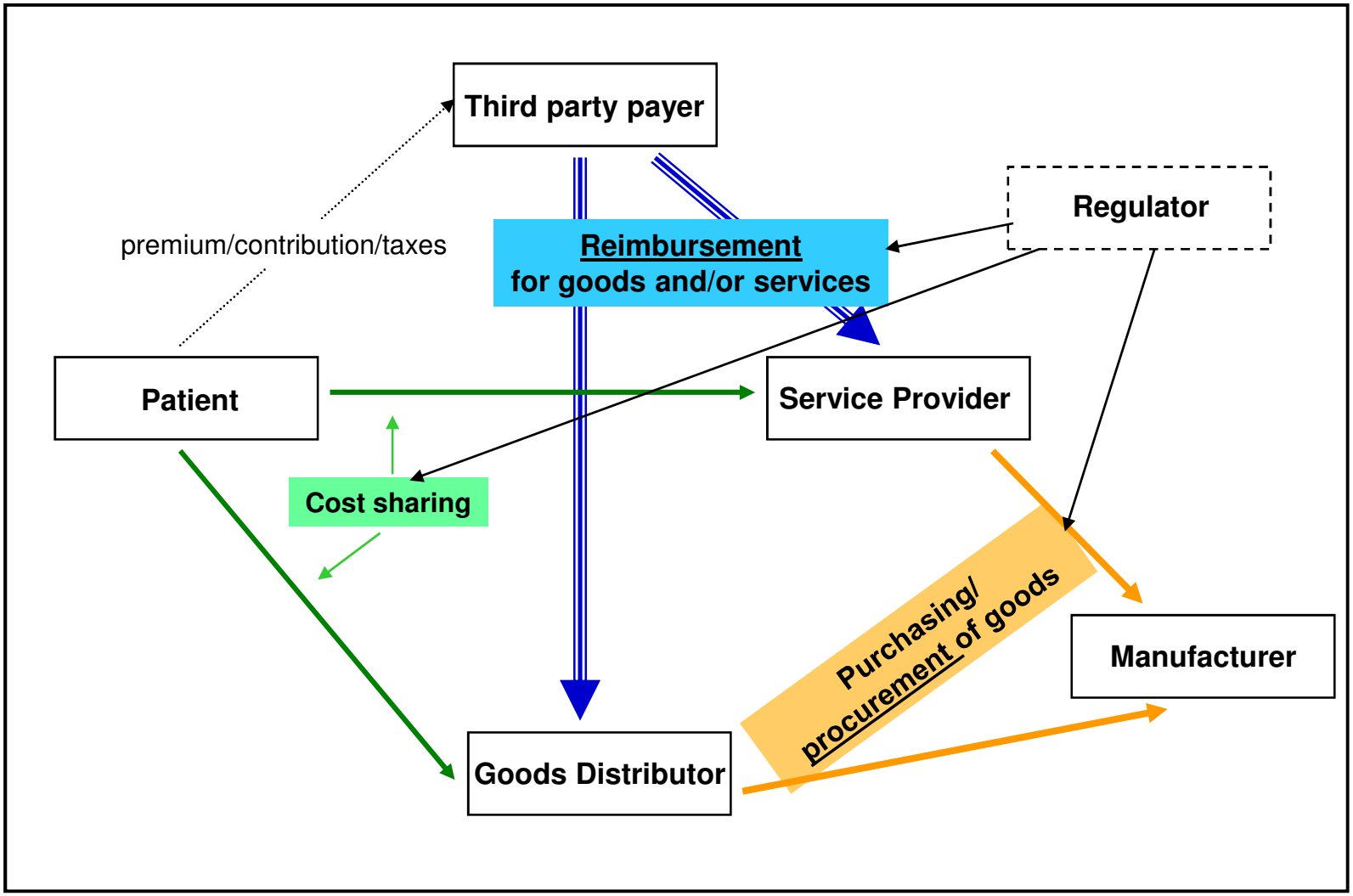
Category III "assistance for professionals"

technical equipment supporting professionals in diagnostics and/or treatment with two-stage financing:
- IIIa: investment
- IIIb: refinancing via use (diagnostics/treatment)

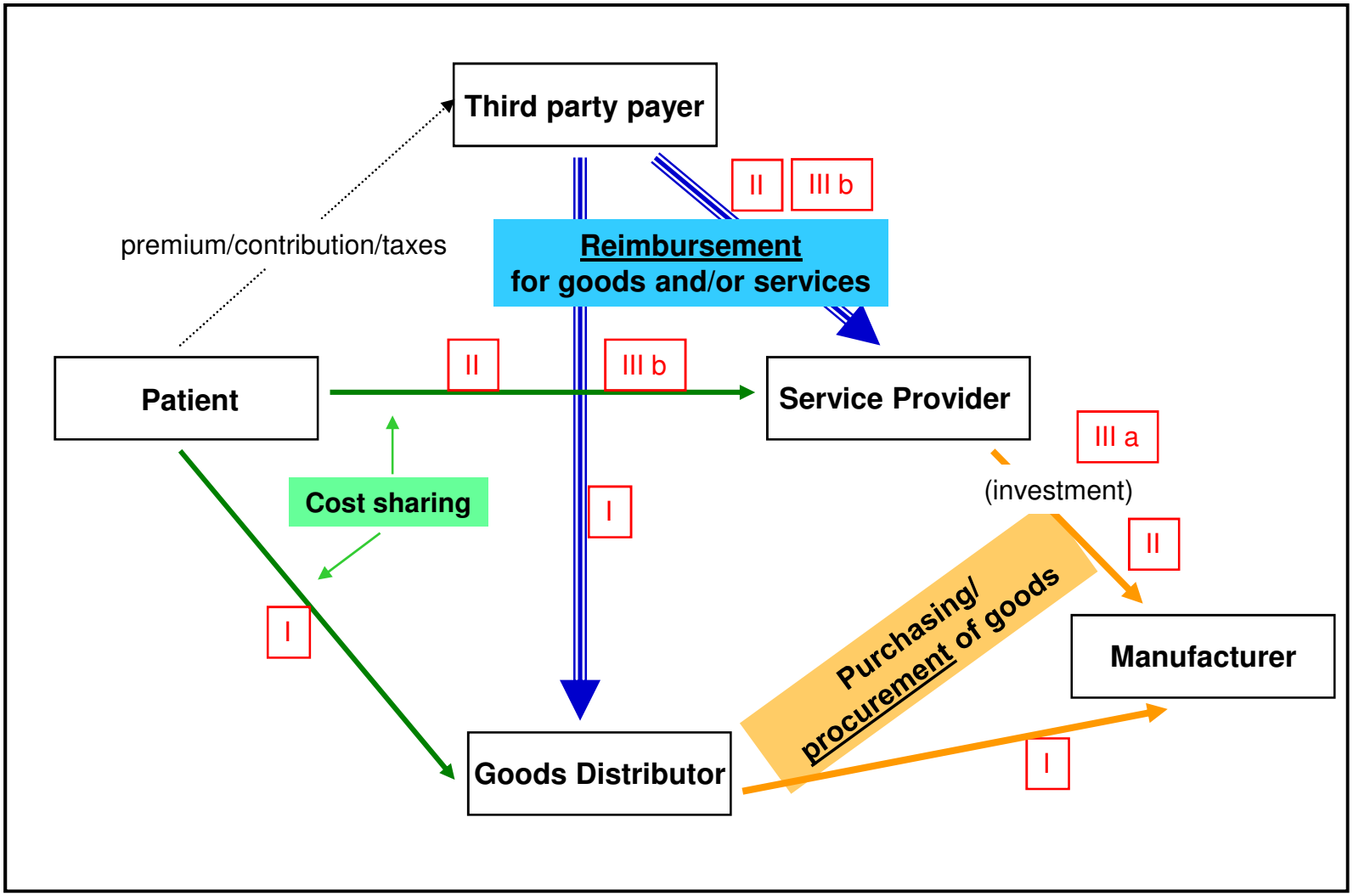
For discussion:
separation in actual "assisting" technologies (e.g. endoscope, ehealth solutions) **and high technology** (e.g. scanner, OR equipment)

- operating room equipment
- imaging devices: X-ray, CT, MRI

Relationships between patients, payers, providers, manufacturers and distributors of medical devices



Relationships between patients, payers, providers, manufacturers and distributors of medical devices

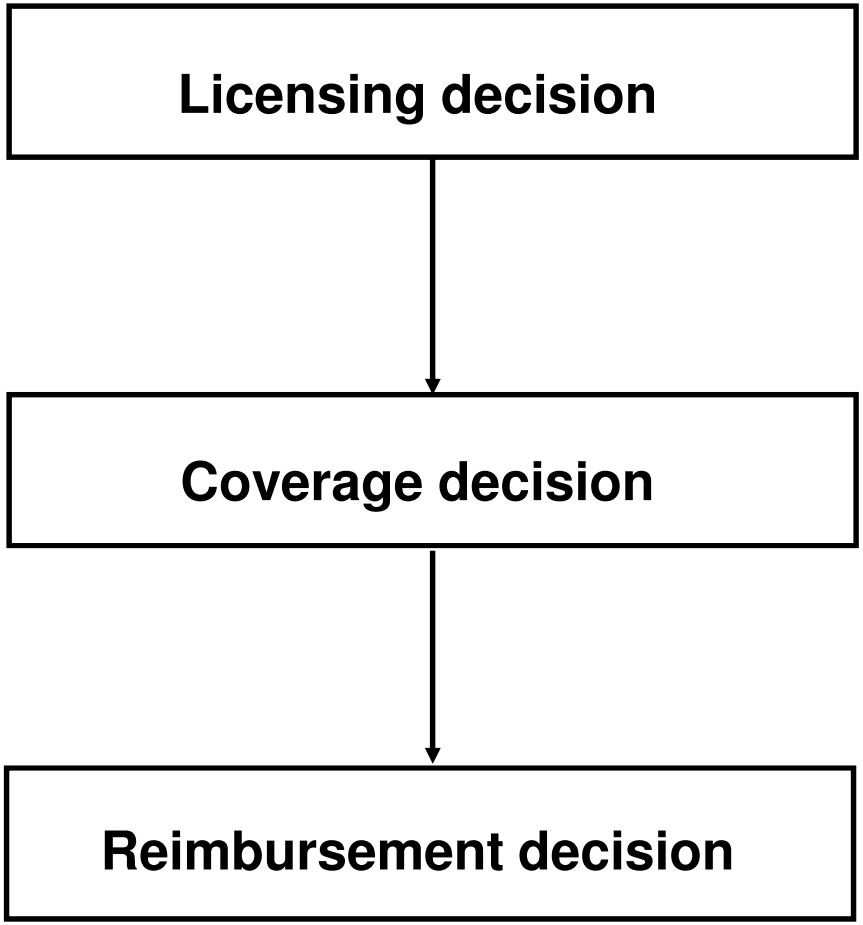


Note: the numbers I, II, IIIa and IIIb refer to the technology categories in previous figure

Together for health innovation

Technische Universität Berlin

But the world of medical devices is more complex …



Licensing decision in the EU

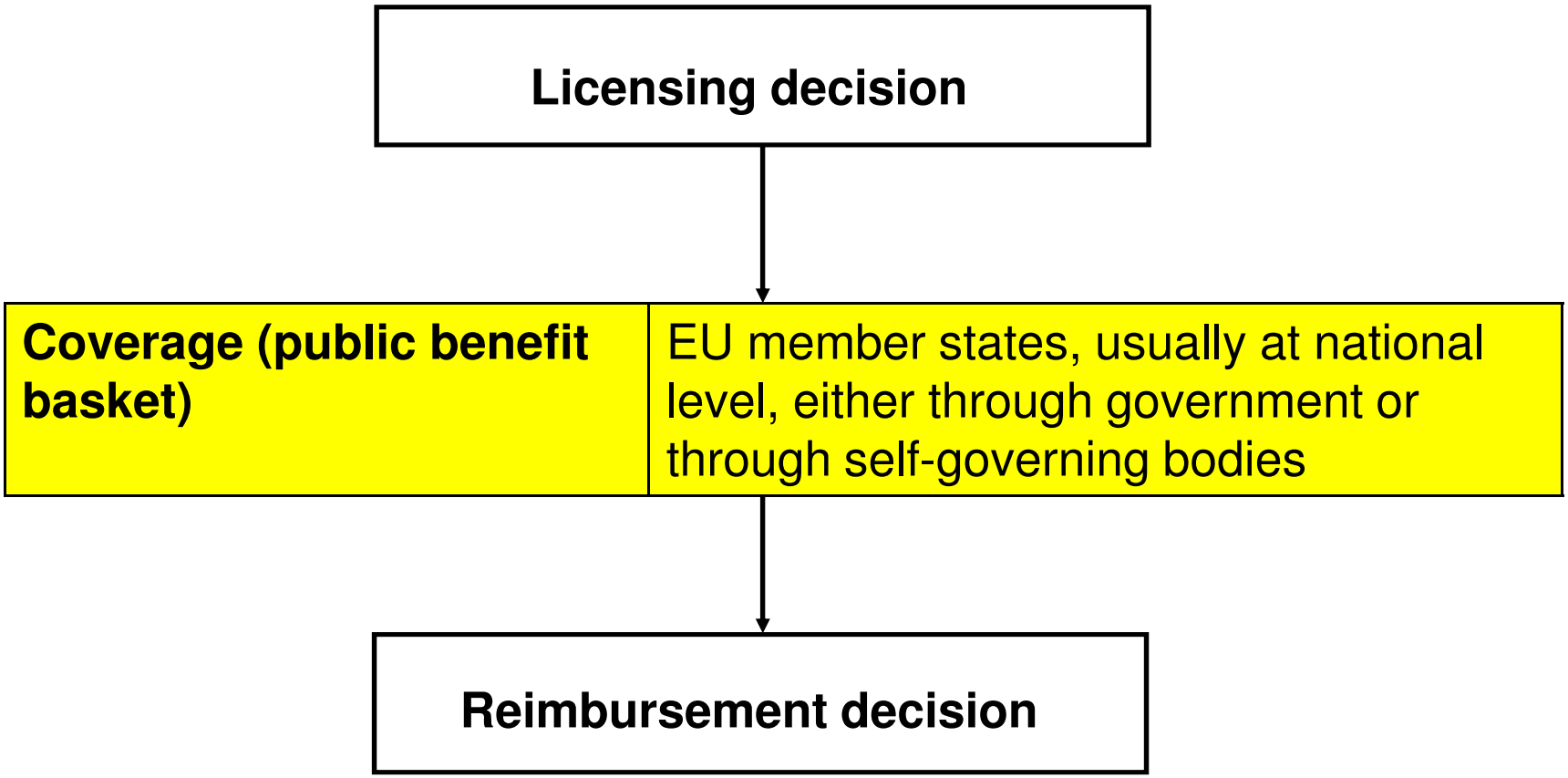
Licensing regulation	EU regulation (medical devices directives), transp… l law
Actual licensing decision on a certain medical device	Notified bodies in… s (but decision is also v… countries) – decisi… …safety concerns, functionality, product quality

Not effectiveness/ medical benefit to patient

Coverage decision

Reimbursement decision

Coverage decision in the EU



Decisions on coverage of medical devices – usage of Health Technology Assessment (HTA)

medical technologies

Category I
"medical aids"

standard products which are prescribed and given to an individual patient
-> device = benefit in basket

Little HTA

Category II
"artificial ... rts"

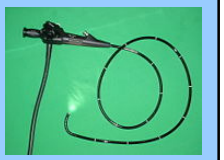
med...

Currently role for HTA, typically for indication/ service/product combination

Service (not product) is focus of HTA

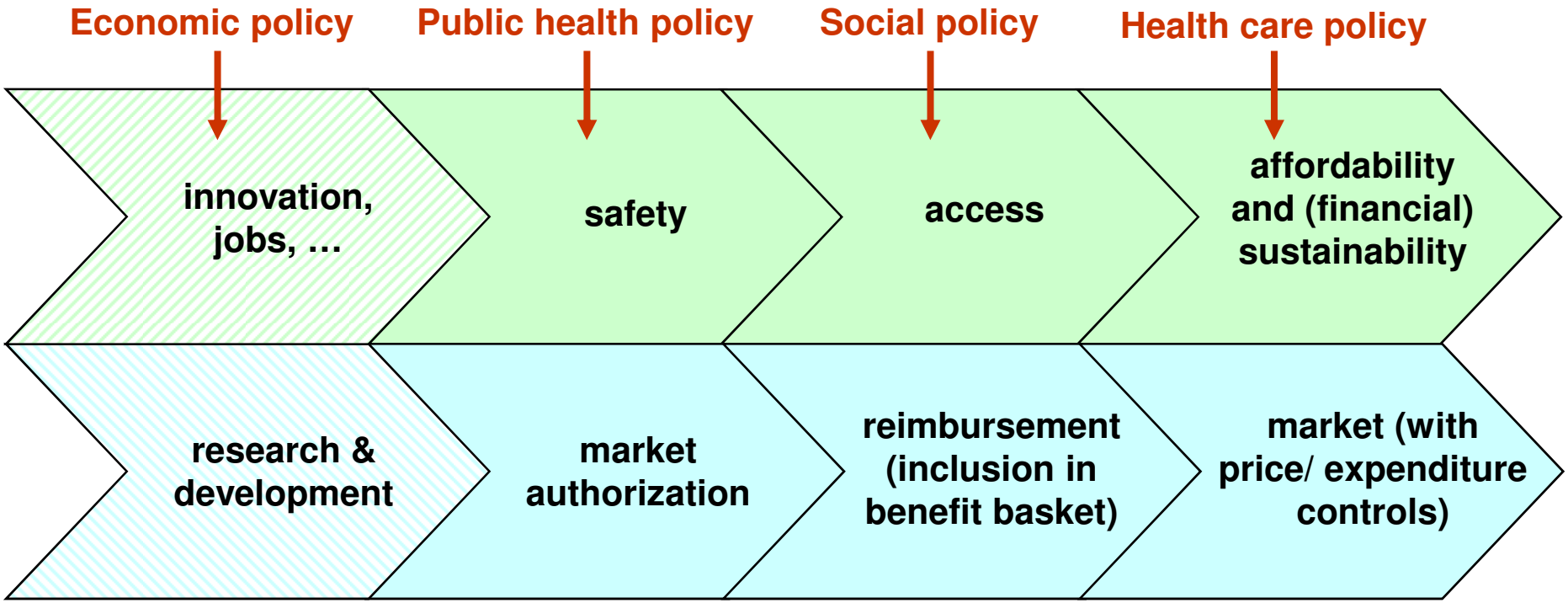
Category III
"assistance for professionals"

...nical equipment
...g professionals in
...d/or treatment
...nancing:
...stment
...refinancing via use (diagnostics/treatment)

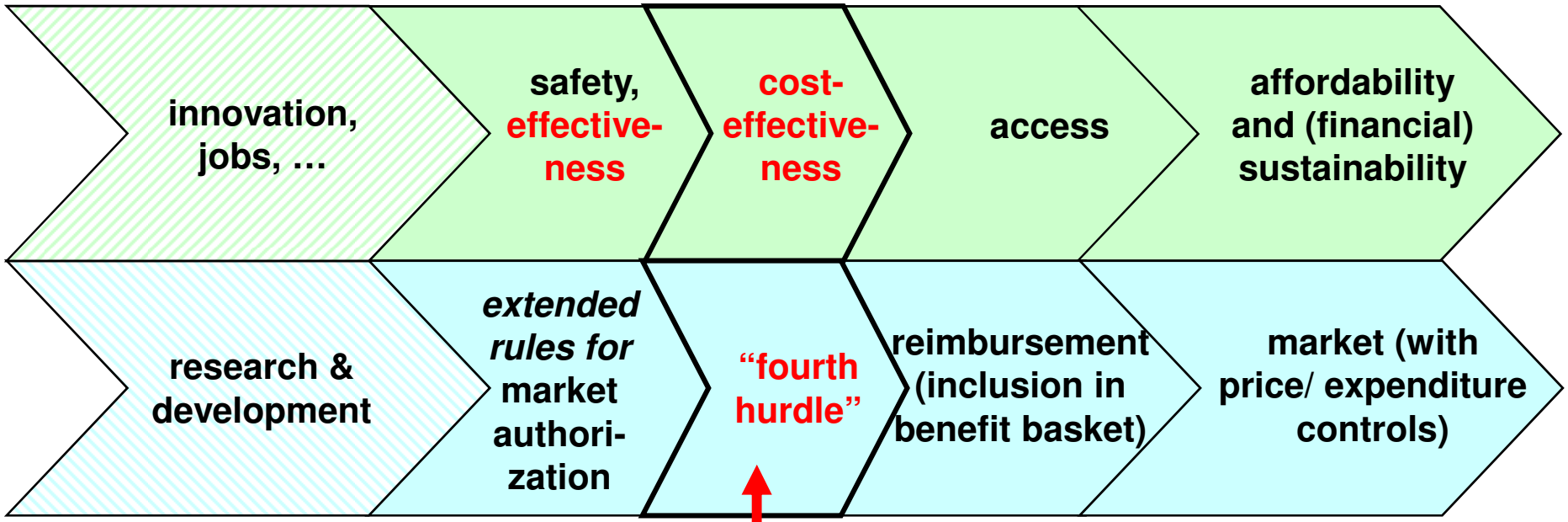


Limitations to particular patients, products or service providers possible

Currently …


Economic policy
Public health policy
Social policy
Health care policy
innovation, jobs, …
safety
access
affordability and (financial) sustainability
research & development
market authorization
reimbursement (inclusion in benefit basket)
market (with price/ expenditure controls)

… and soon
a changing regulatory environment?



… but evaluation is more complex than for pharmaceuticals and cannot be copied!

But are evaluations of medical technologies for HTA possible?

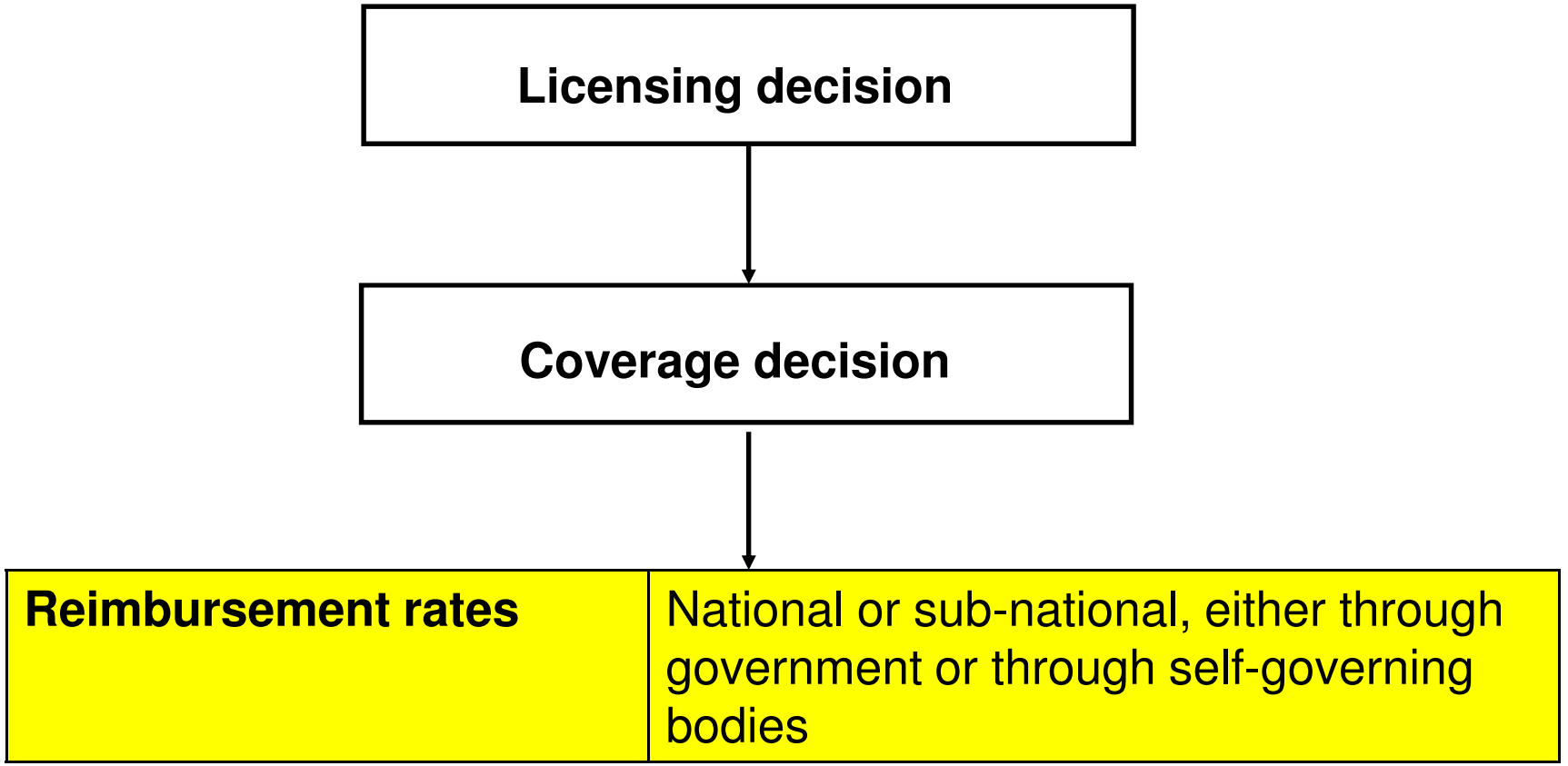
- Short product cycles -> evaluation takes too long and impedes access
- Small patient groups -> randomisation/ control group not possible (untrue!)
- Placebo often not possible -> good use of data under routine conditions necessary!

SOLUTION: include in benefit basket if at least as good as old one; if priced higher, reimburse it only for a limited time and in exchange for proper evaluation

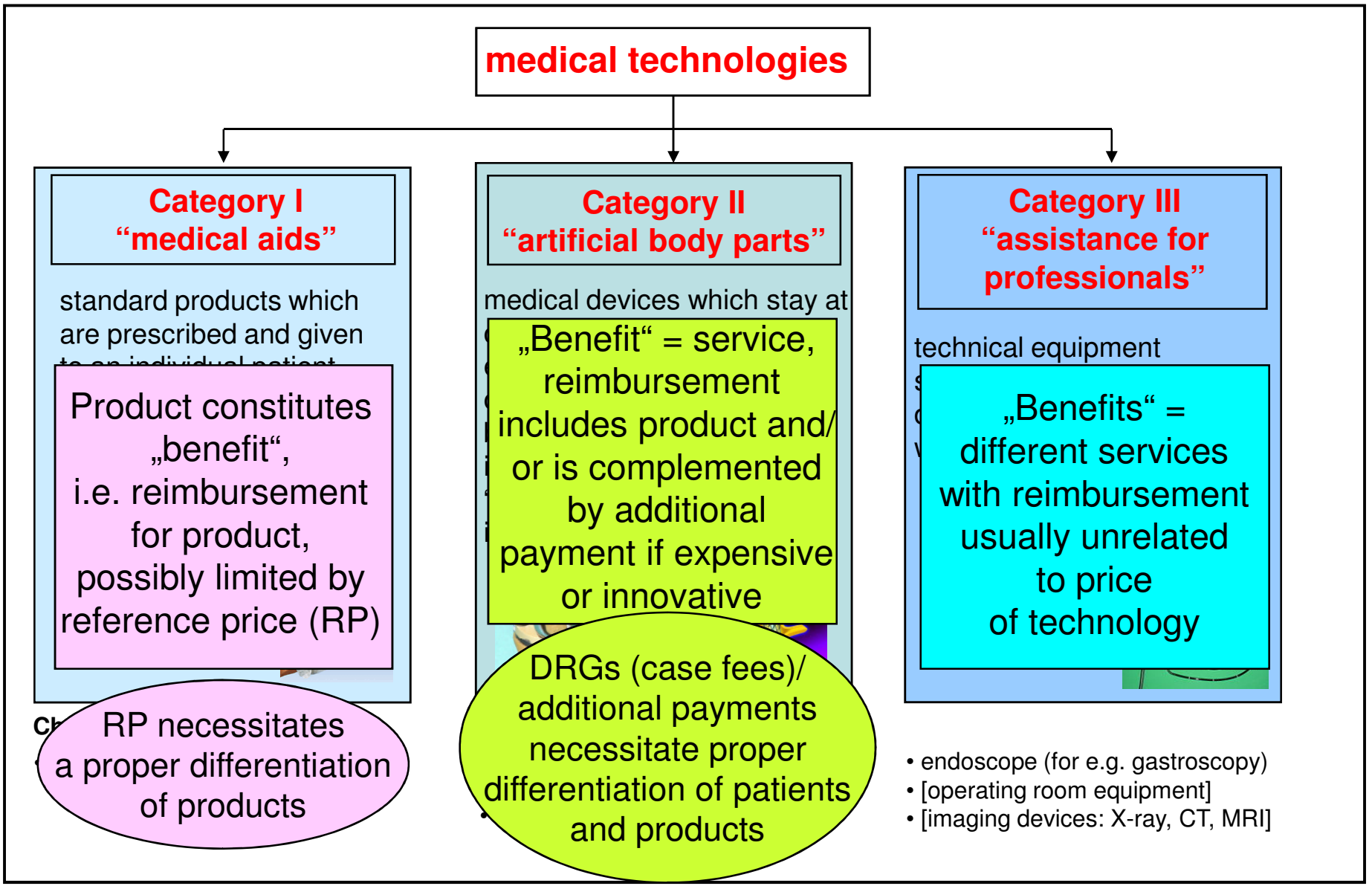
Evaluation of routine care is possible: PTCA only vs. No PTCA

- To give an idea what EHTI results will look like
- Risk-adjustement (propensity score) needs to be improved
- Further variables have to be integrated in the regression
- with stable model comparison to stents (bare metal & DES)

Reimbursement decision in the EU



Reimbursement of medical device technologies



Number of DRGs/HRGs for particular devices

	Germany	Italy	UK
Implantable Cardio-Defibrillator	9	3	2
Knee replacement	13	2	2
Negative pressure/ vacuum therapy	2	-	-

Conclusions

- Medical technologies play an important part of health care
- … but variable terminology and regulatory framework leads to misunderstandings and
- both under- and overestimation of benefit

-> coherent framework necessary

-> proper evaluation necessary, but methodology cannot be copied

-> important role for health and cost data gathered under routine conditions