

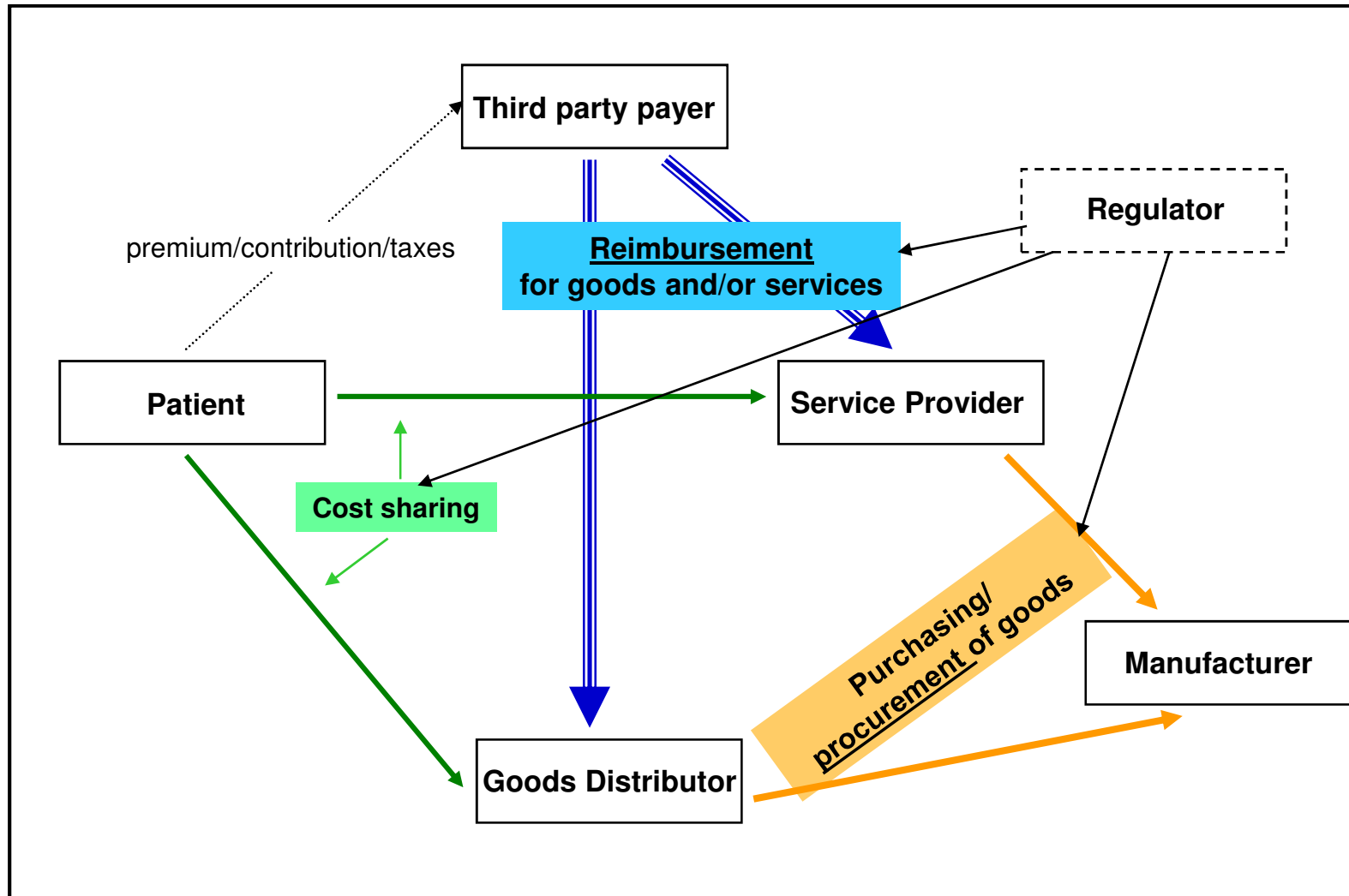
Decision-making: the link between reference pricing and procurement

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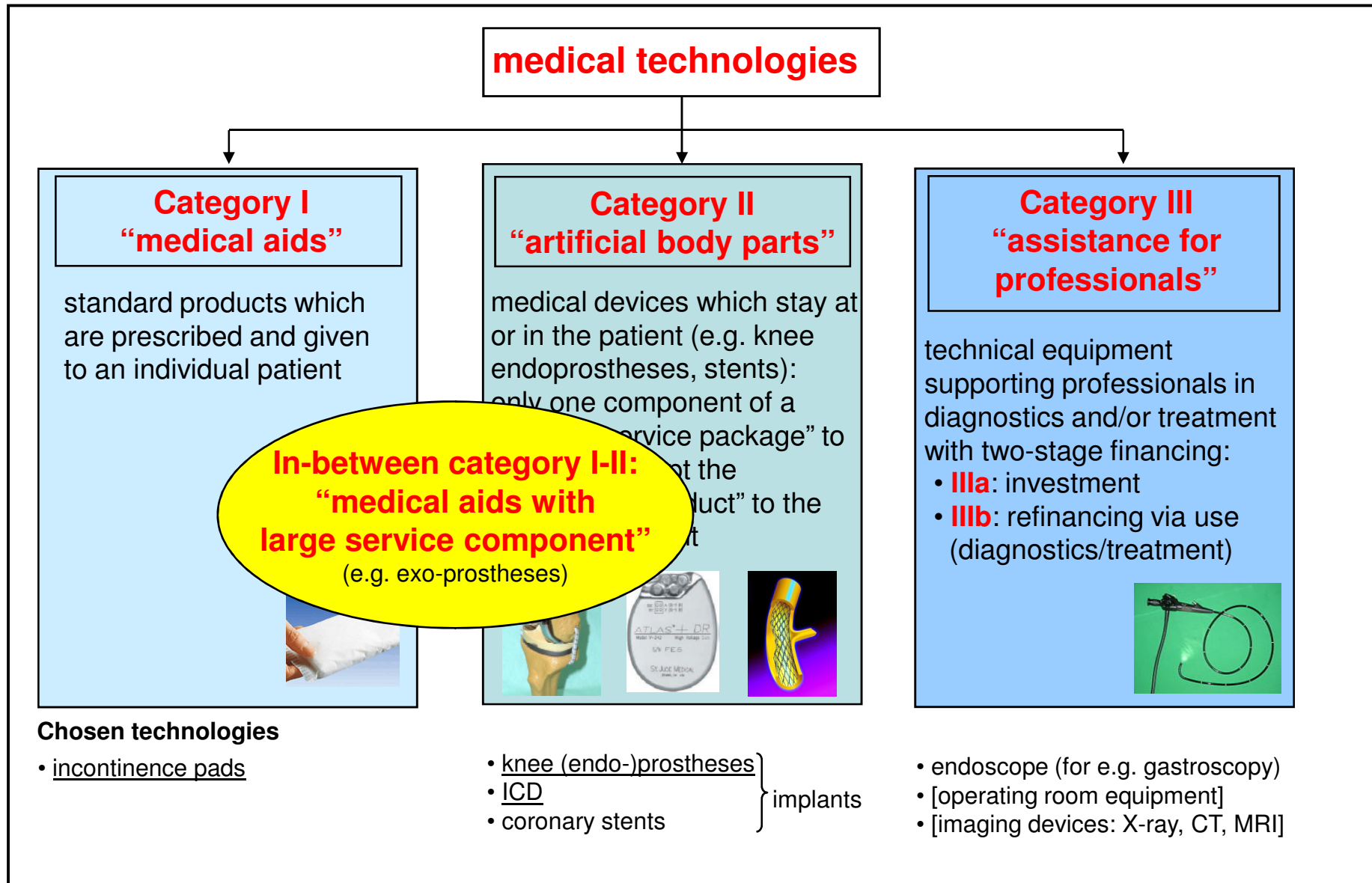
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Relationships between patients, payers, providers, manufacturers and distributors of medical devices

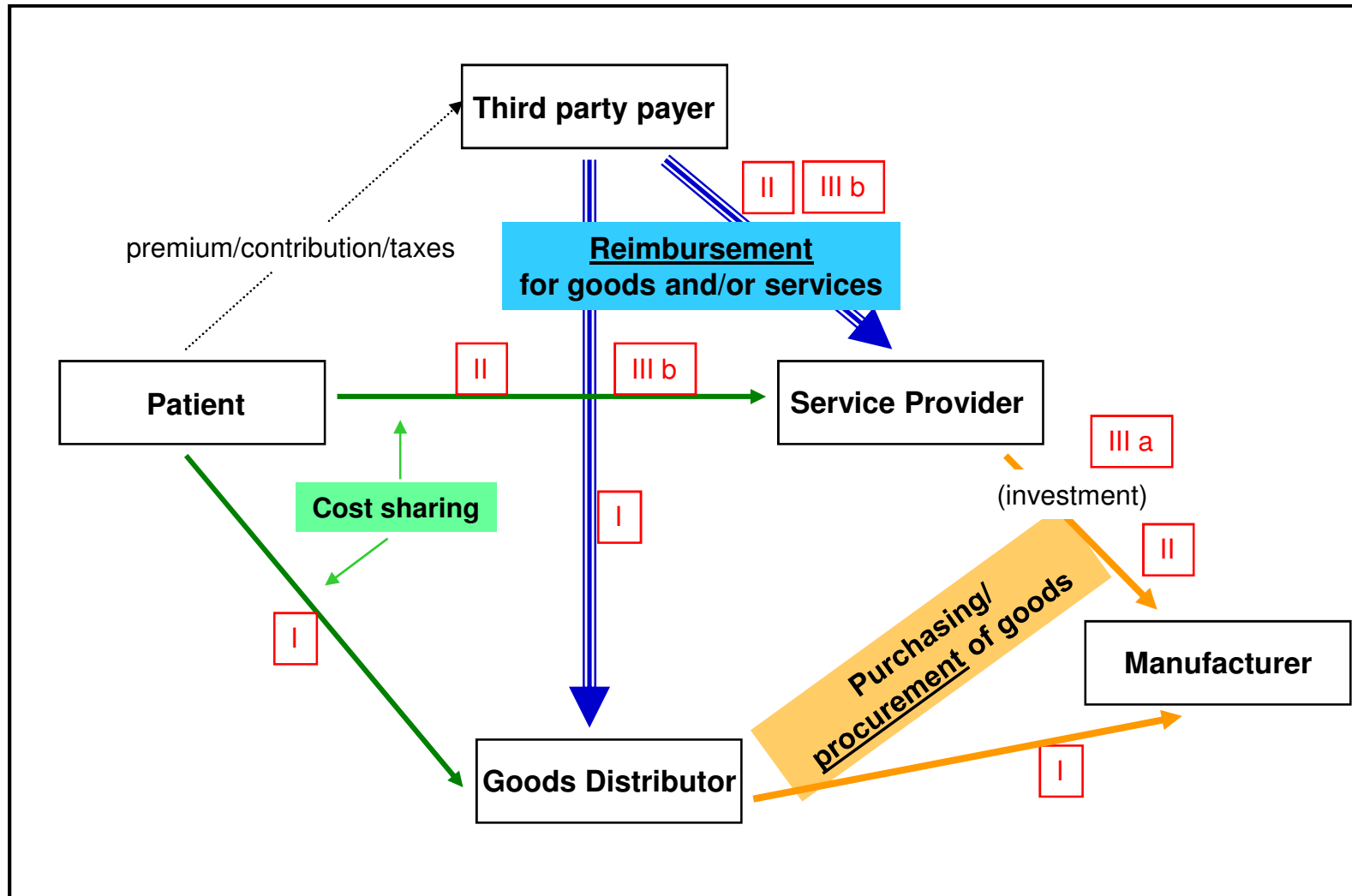


- First observation: complicated relationships, varying among medical technologies (and countries)
- Second observation: complicated/ confusing terminology – What is procurement? What is price? What is reference price? Does it refer to reimbursement or procurement?



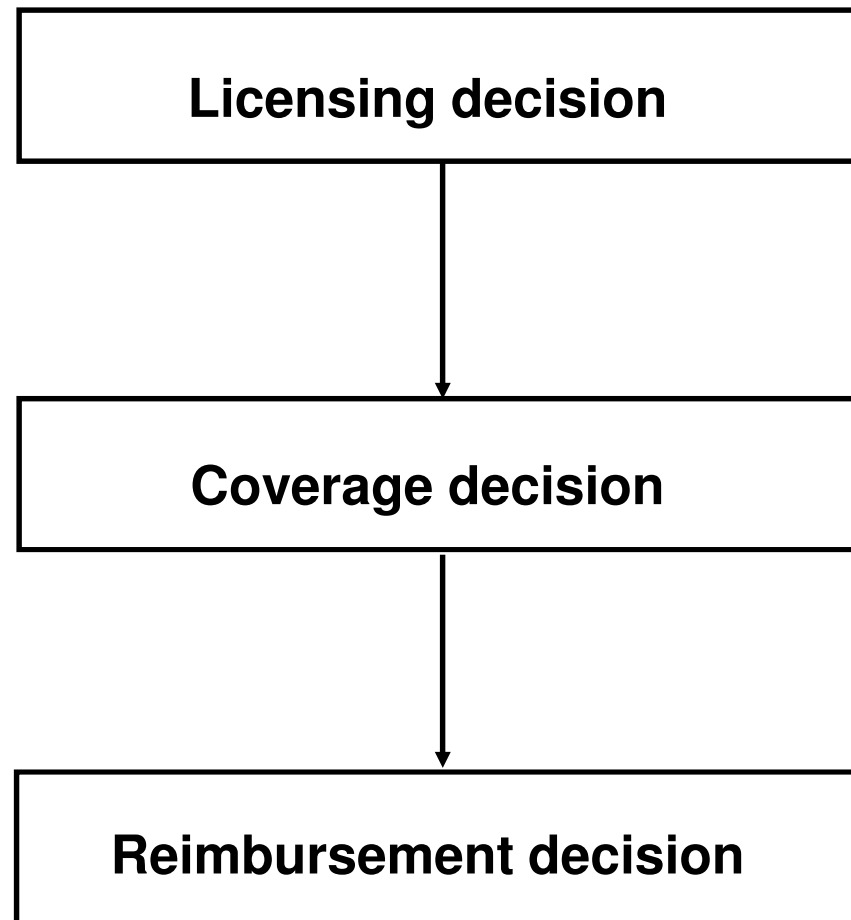
Note: underlined technologies are part of the first part of the project

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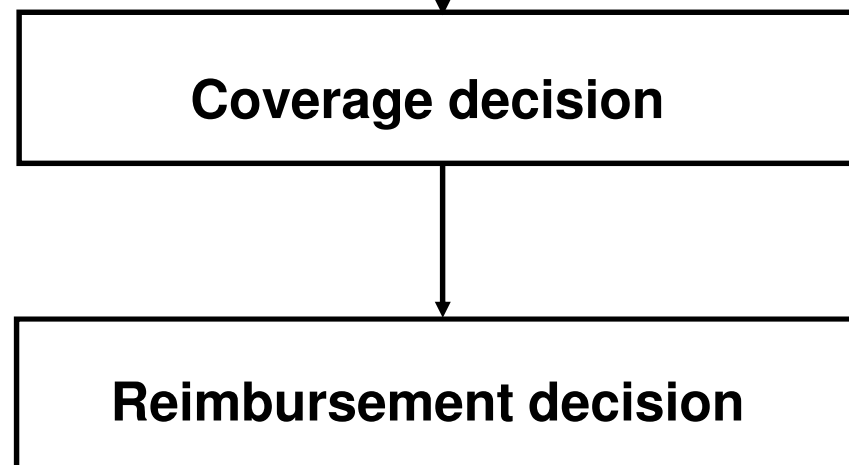


Note: the numbers I, II, IIIa and IIIb refer to the technology categories in previous figure

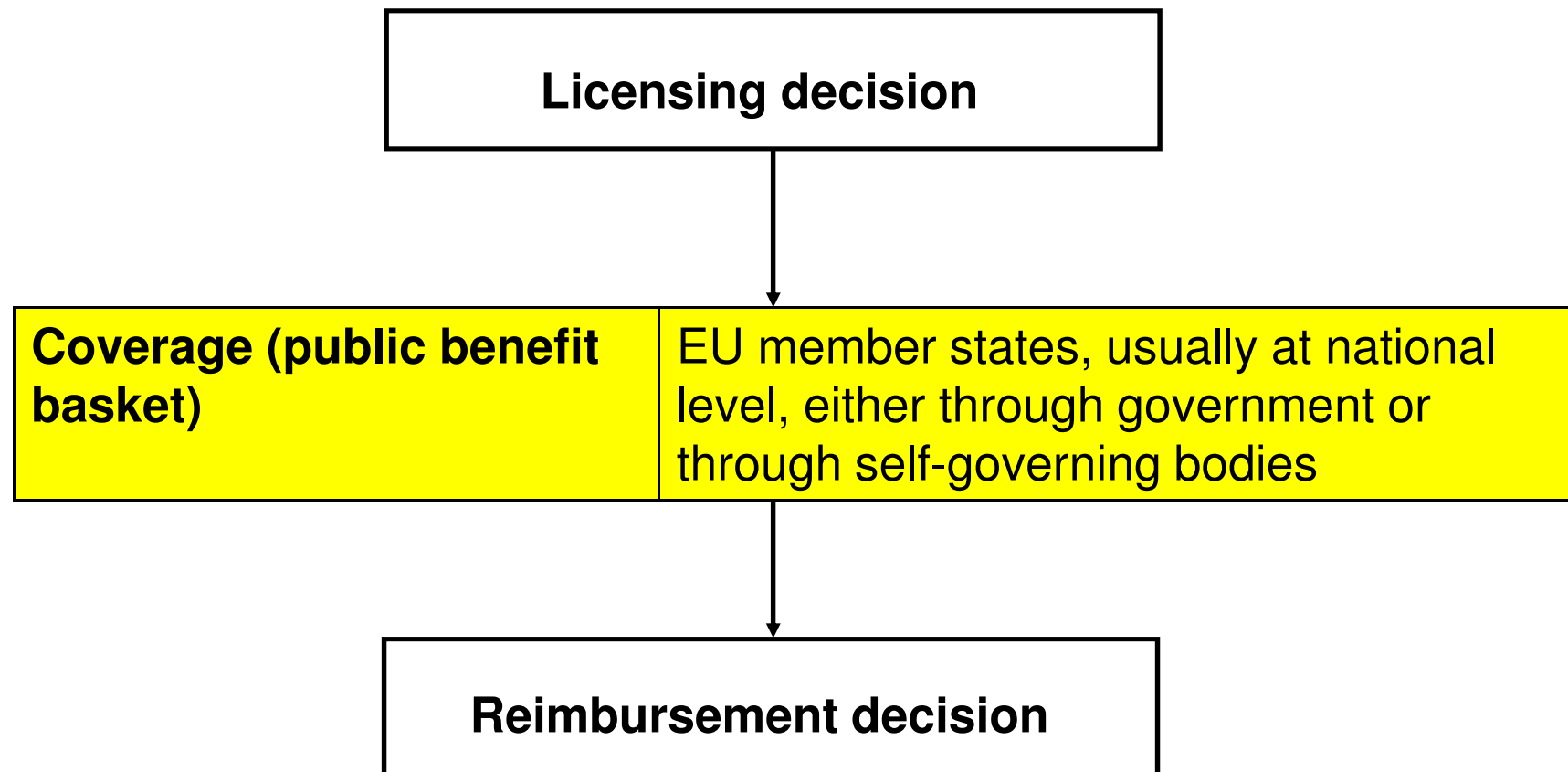
But the world of medical devices is more complex ...



Licensing regulation	EU regulation (medical devices directives), transposed into national law
Actual licensing decision on a certain medical device	Notified bodies in 27 member states (but decision is also valid in all other 26 countries) – decision depends on safety concerns, functionality, product quality



Coverage decision in the EU



How is the benefit basket structured? What is the taxonomy? How explicit is it?

Figure 1. Spanish Health Basket

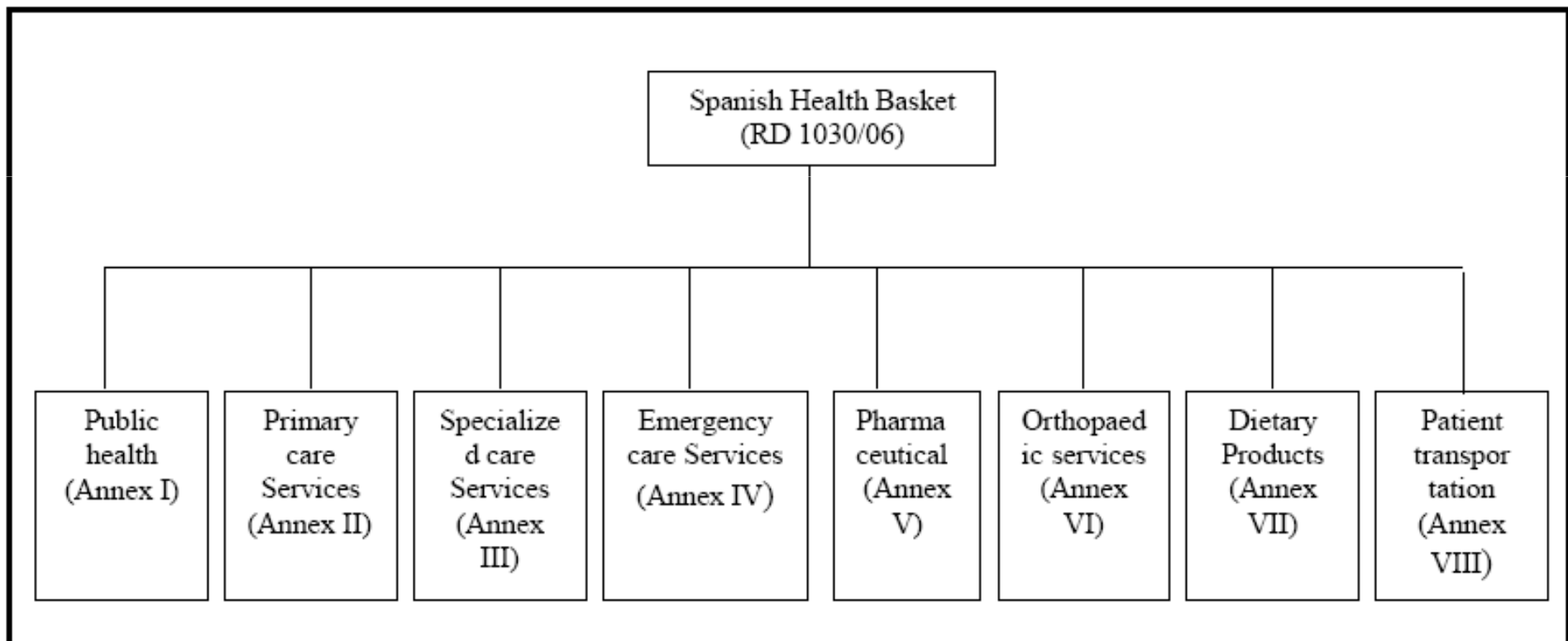
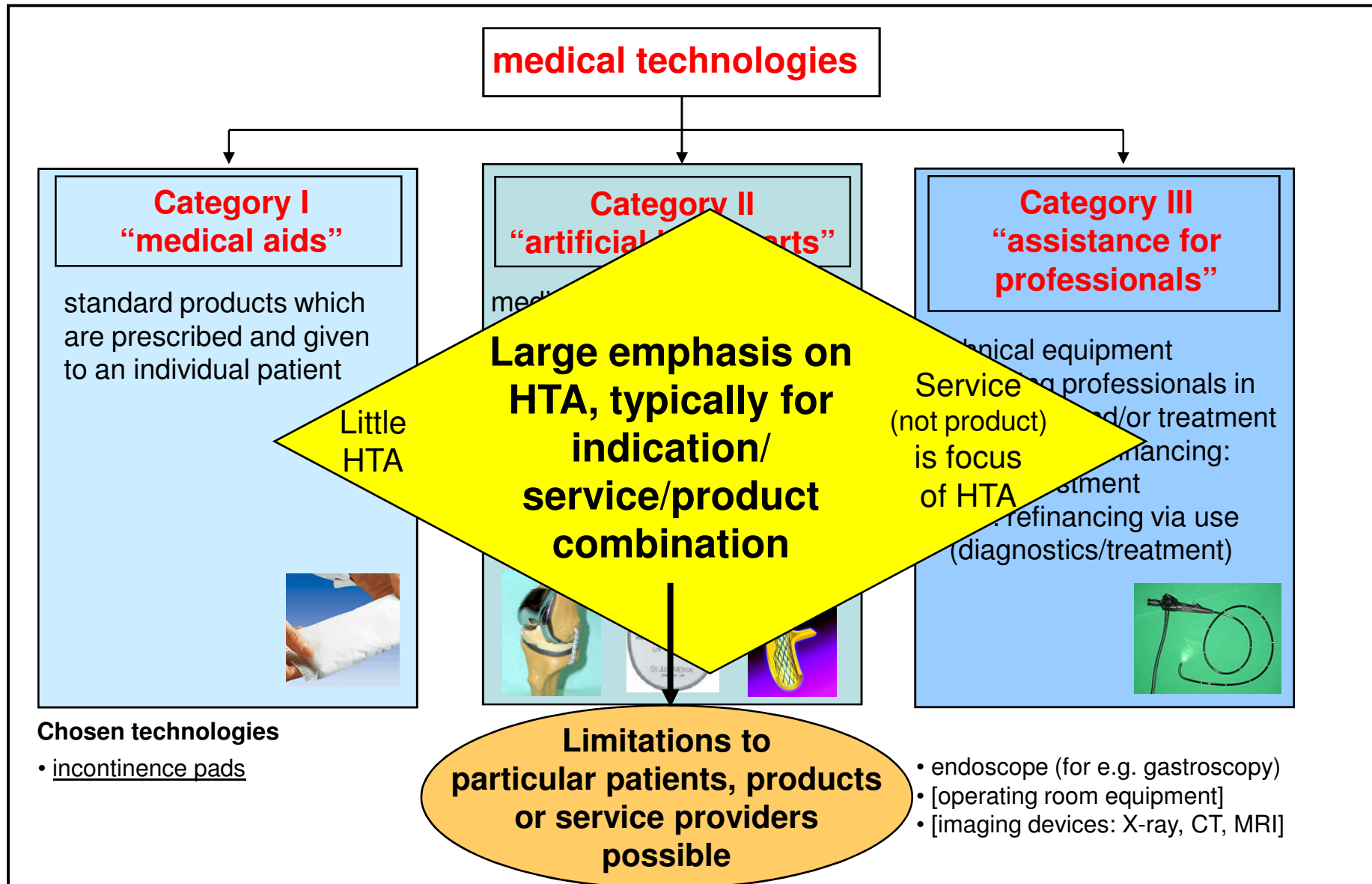


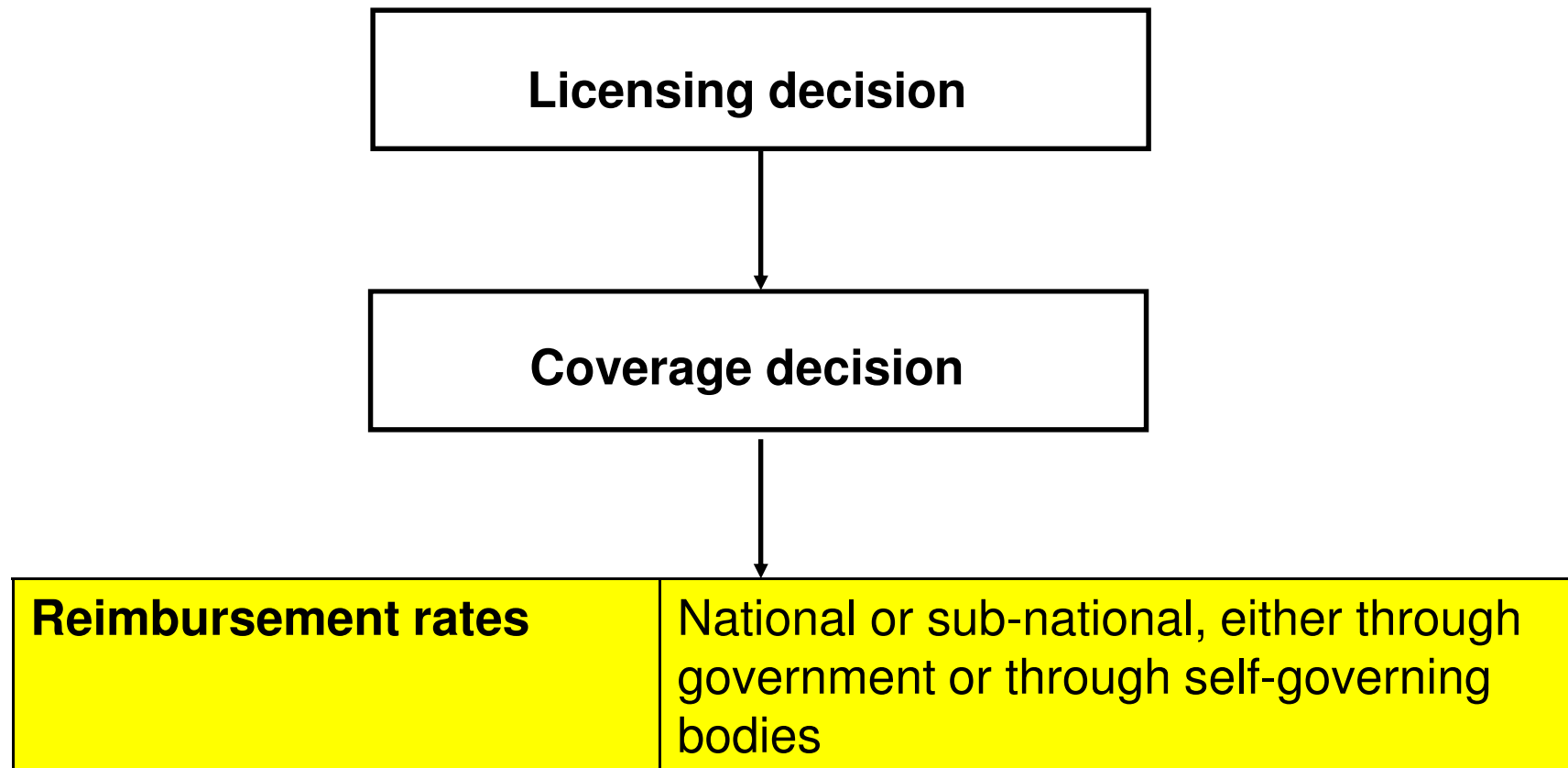
Table 11: Key regulatory frameworks defining the health basket

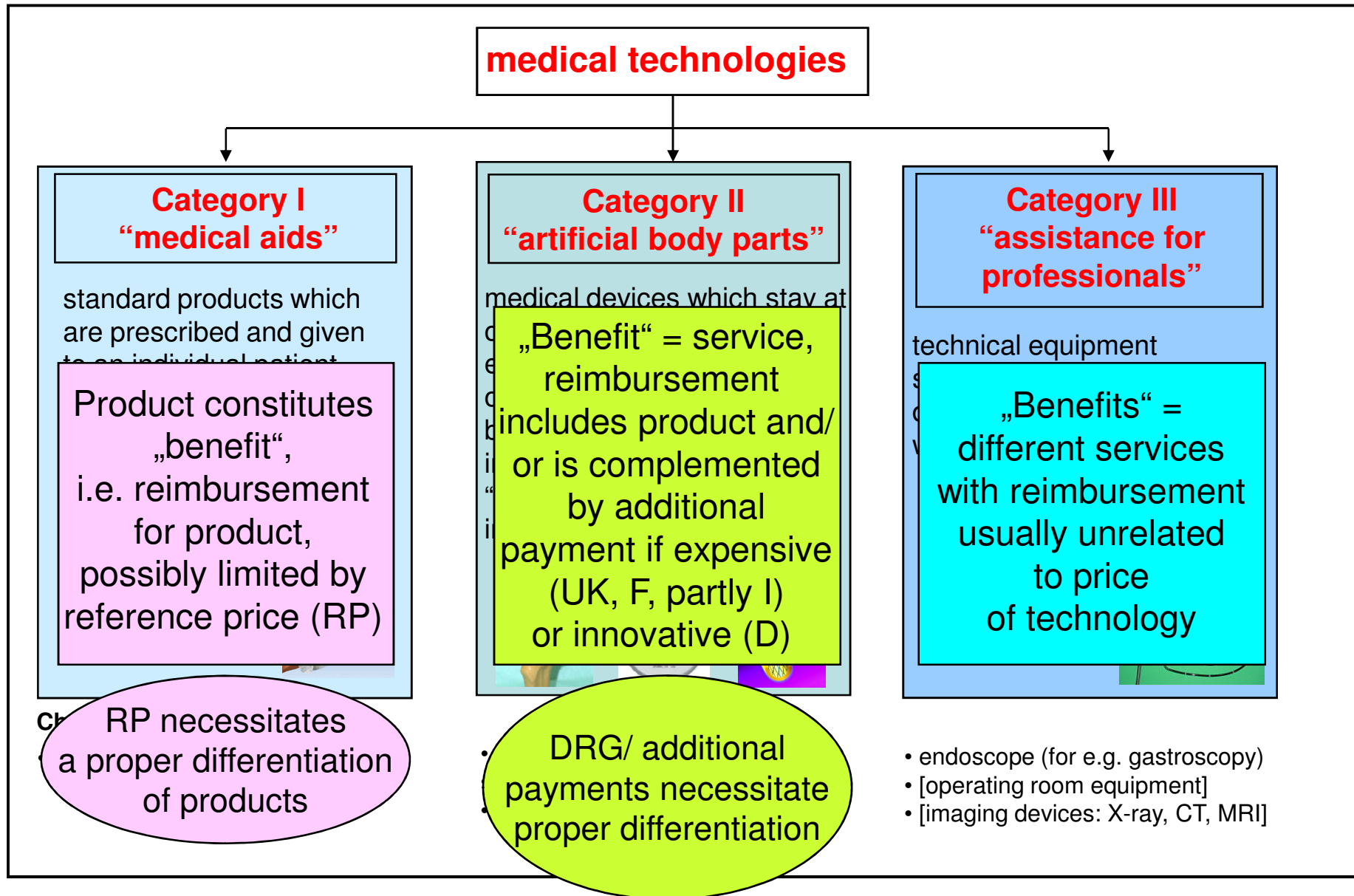
Type of Framework/Document	Acts of Parliament	Statutory Instruments (SI)	Directives	National Service Frameworks	NICE guidance	Contracts	HRG Tariffs	Drug Tariff	Fee Schedules
Legally-binding	Y	Y	Y	N	Y (only technology appraisals)	Y	N	N	N
Decision-makers	Parliament	Parliament	Secretary of State; SHAs; Monitor	DII; external reference groups	DH; Appraisal Committee; National Collaborating Centres; Advisory Committee; stakeholders	DH; professional bodies and associations	DH	Secretary of State for Health; PPD	DH; professional bodies and associations
Original purpose	Establishes duties and powers for broad categories of care	Clarify or amend primary legislation	Direct action of NHS bodies	Improve quality and decrease variation of services	Improve quality and decrease variation of services	Reimbursement	Reimbursement	Reimbursement	Reimbursement
Positive or negative definition of benefits	P	P/N	P	P	P/N	P	P	P	P
Degree of Explicitness*	1	1-3	2	2 or 3	2 or 3	1-3	2 or 3	3	3
Itemized: Goods, Procedures, Indications		Goods and procedures		Goods and procedures	Goods and procedures	Procedures	Procedures	Goods	Procedures
Updating	Irregular	Irregular	No	Unclear	Every 4 to 6 years	Infrequent	Still evolving	Monthly	Annually
Criteria for Defining Benefits	Political judgment; 'necessary to meet all reasonable requirements'	Need, costs, cost-effectiveness, budget, safety	Need, effectiveness, budget	Need and effectiveness	Costs, effectiveness, and cost-effectiveness	Need and budget	Costs and budget	Costs, cost-effectiveness, budget, safety, quality, and appropriateness	Need and budget

*1=all necessary, 2=areas of care, 3=items.



Reimbursement decision in the EU

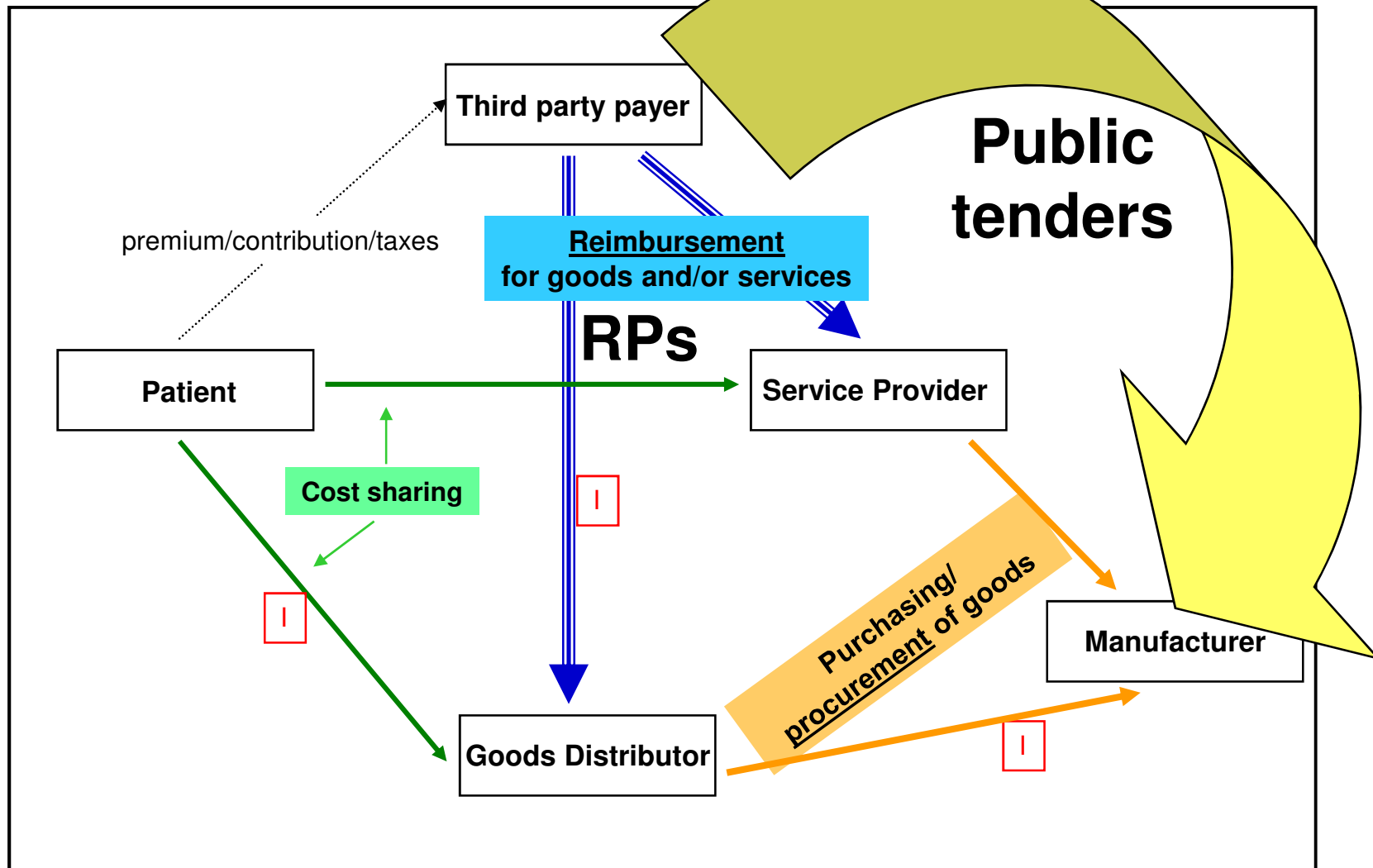




Reimbursement of medical aids in Germany

- Sickness funds shall implement public tenders for standardized products
- Sickness funds shall conclude contracts for further products
- Sickness funds shall conclude individual contracts for products with high service intensity (e.g. exoprostheses)
- For certain categories of products, RPs exist. If contracts based on tenders are concluded for these categories, these RPs serve as maximum prices.

Relationships between patients, payers, providers, manufacturers and distributors



Reference prices for medical aids in Germany

- There are reference prices (RPs) for 6 out of 33 categories of medical aids
- RPs serve as a reimbursement limit
- Products are grouped in homogeneous classes; for each group, reference prices are set (based on current market)

Reference prices for Incontinence Pads in Germany

Number of position	Term	Reference price [€] [each]
15.25.01	absorptive incontinence pad	
15.25.01.0	Anatomical formed incontinence pad, normal absorptive capacity, size 1	0.29
15.25.01.1	dito., size 2	0.35
15.25.01.2	dito., size 3	0.43
15.25.01.3	rectangular formed incontinence pad, size 1	0.19
15.25.01.4	rectangular formed incontinence pad, size 2	0.23
15.25.01.5	incontinence pad for urinary incontinence	0.21
15.25.03	absorptive incontinence pants	
15.25.03.0	incontinence pants, size 1	0.49
15.25.03.1	incontinence pants, size 2	0.51
15.25.03.2	incontinence pants, size 3	0.69

Reference prices for Incontinence Pads in Spain

Table 25 Urinary incontinence pads in Spain – reimbursable products

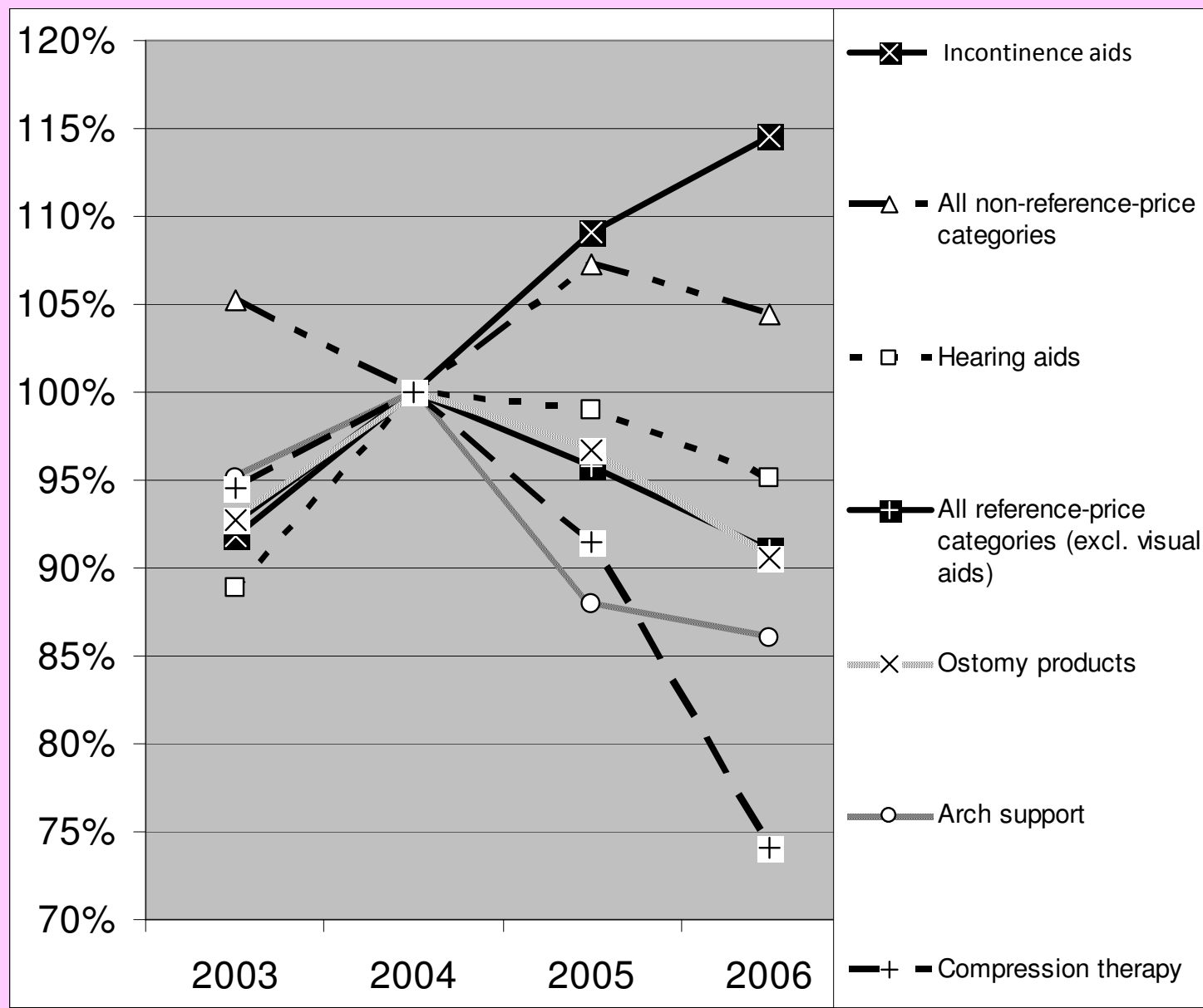
TYPE OF PAD		ABSORPTION RATE (cc)	MAXIMUM PRICE PER UNIT (Pesetas)
DAY for medium incontinence	Rectangular	600 – 900	65
	Anatomic Shaped	600 – 900	78
NIGHT for medium nightly or heavy daily incontinence	Rectangular	900 – 1200	92
	Anatomic Shaped	900 – 1200	110
SUPER NIGHT for heavy night incontinence	Rectangular	More than 1200	109
	Anatomic Shaped	More than 1200	132

Source (INSALUD 1988)

Reference prices for medical aids in Germany

- There are reference prices (RPs) for 6 out of 33 categories of medical aids
- RPs serve as a reimbursement limit
- Products are grouped in homogeneous classes; for each group, reference prices are set (based on current market)
- Manufacturers have a voice in this process
- Patients have to make co-payments
- Patients are free to choose any product with a price higher than the RP if they are willing to pay the difference between the actual selling price and the RP

Medical Aids: Expenditures from public sources under the German RP regime



Number of DRGs/HRGs for particular devices

	Germany	Italy	UK
ICDs	9	3	2
Knee replacement	13	2	2
Neg. pres- sure/ vacuum therapy	2	-	-

Innovative devices: knee endoprotheses and coronary stents in Germany

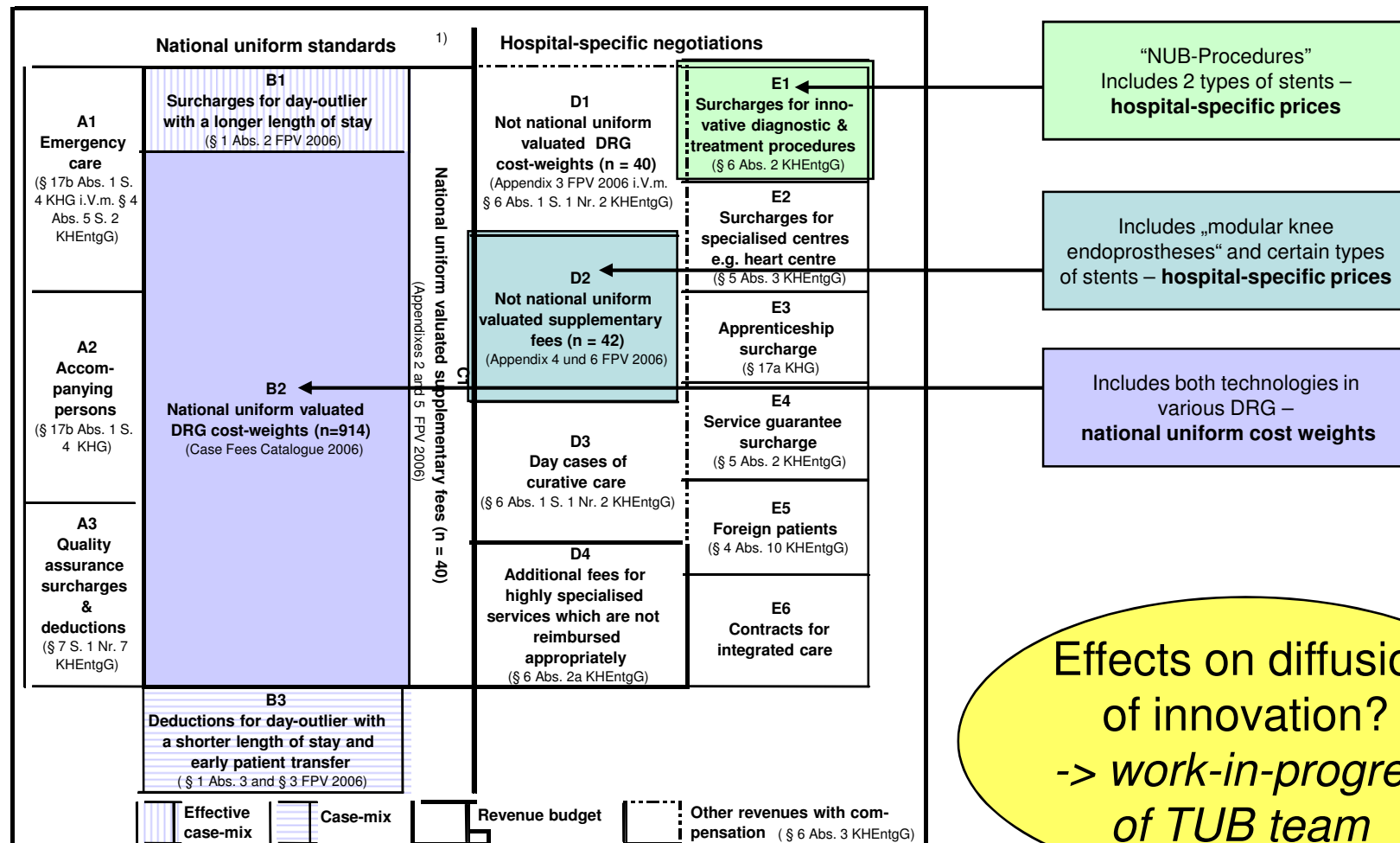
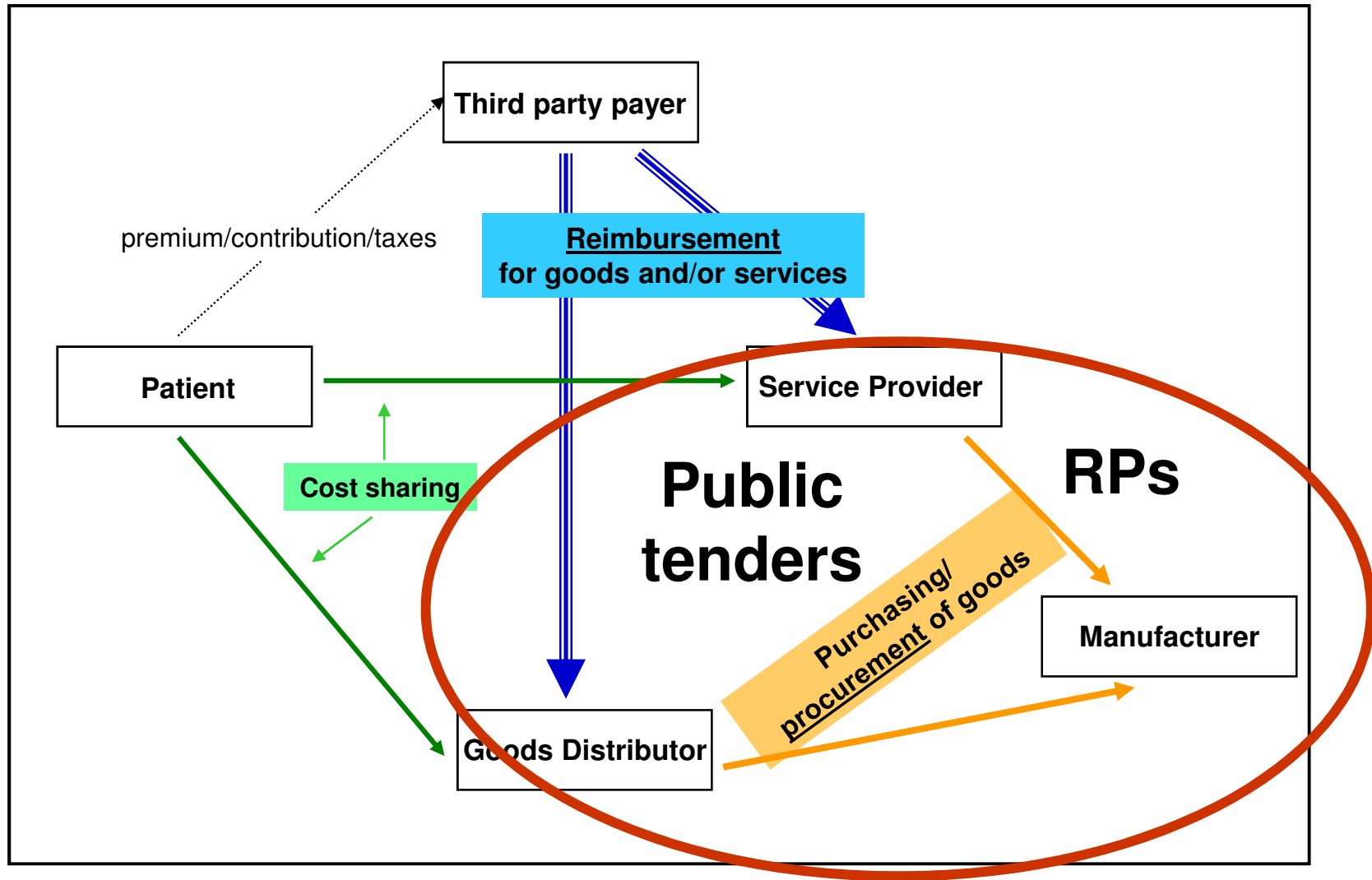
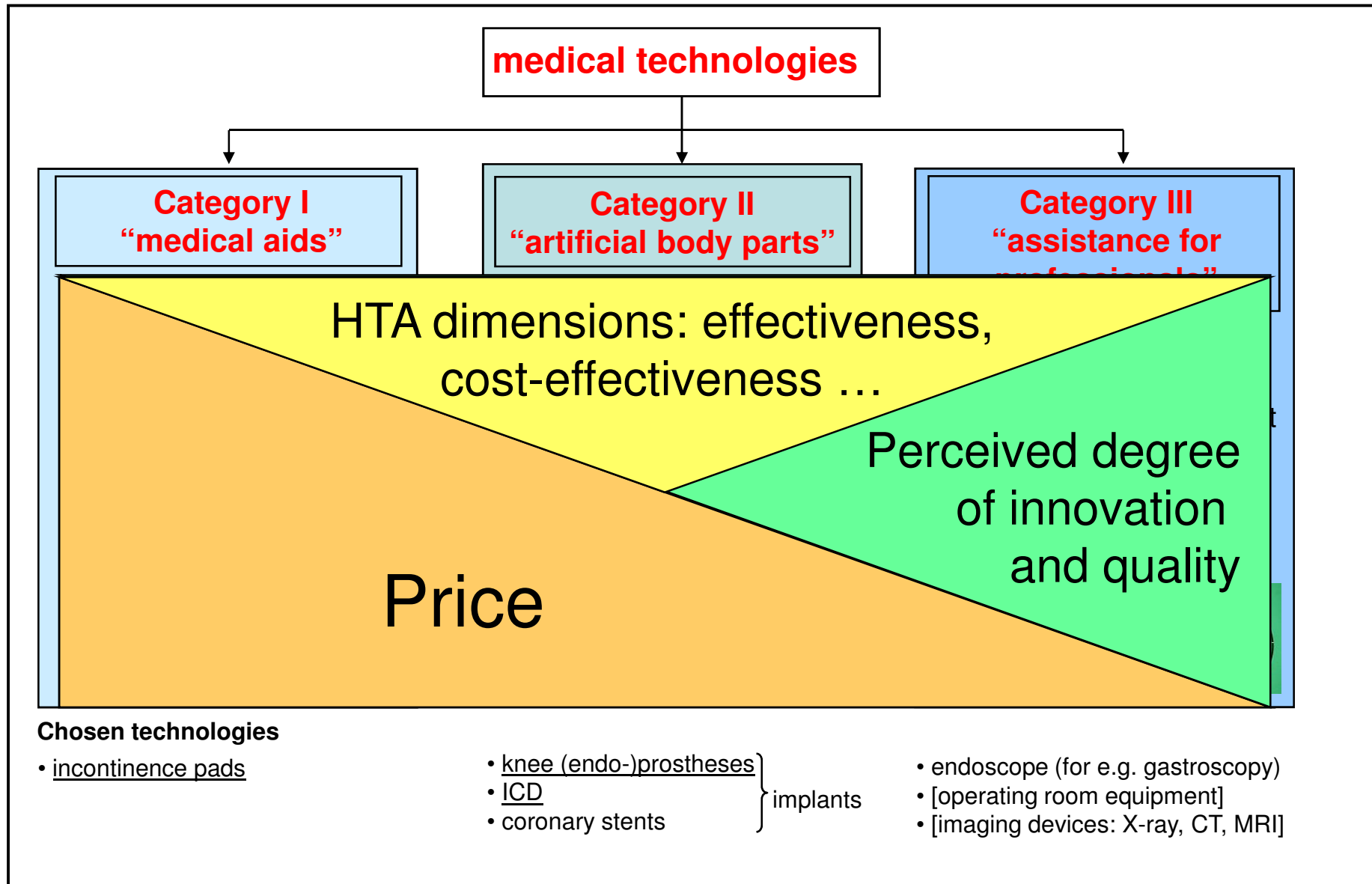


Figure: Reimbursement Components of Inpatient Care in Germany (Schreyögg J, Tiemann O, Busse R (2006) Cost accounting to determine prices: How well do prices reflect costs in the German DRG-system? Health Care Manage Sci 9:269-279. With own adaptations and extensions)

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Purchasing/ procurement criteria for medical device technologies



Note: underlined technologies are part of the first part of the project

Procurement by individual service providers: France

Figure 2: Procurement processes in France

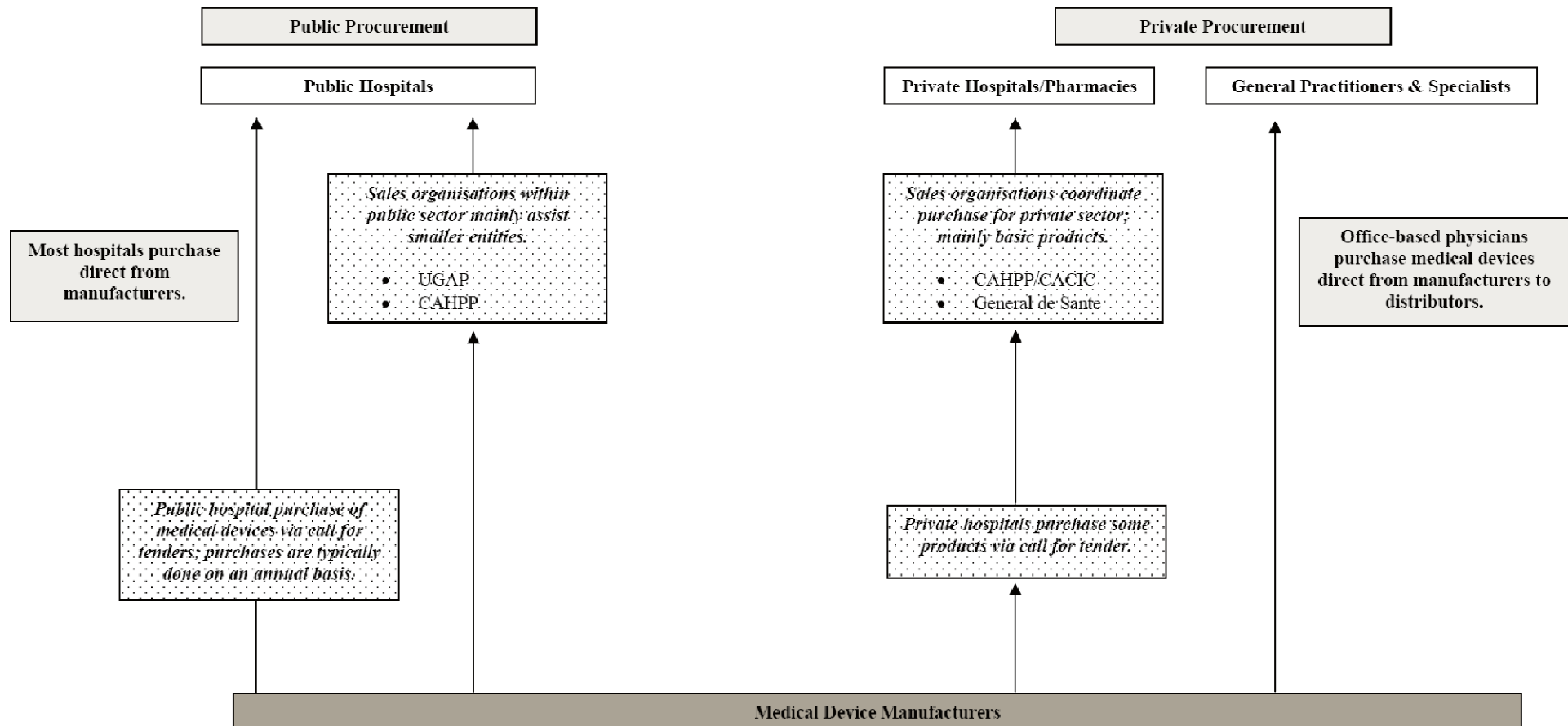


Figure 4: Procurement process in England

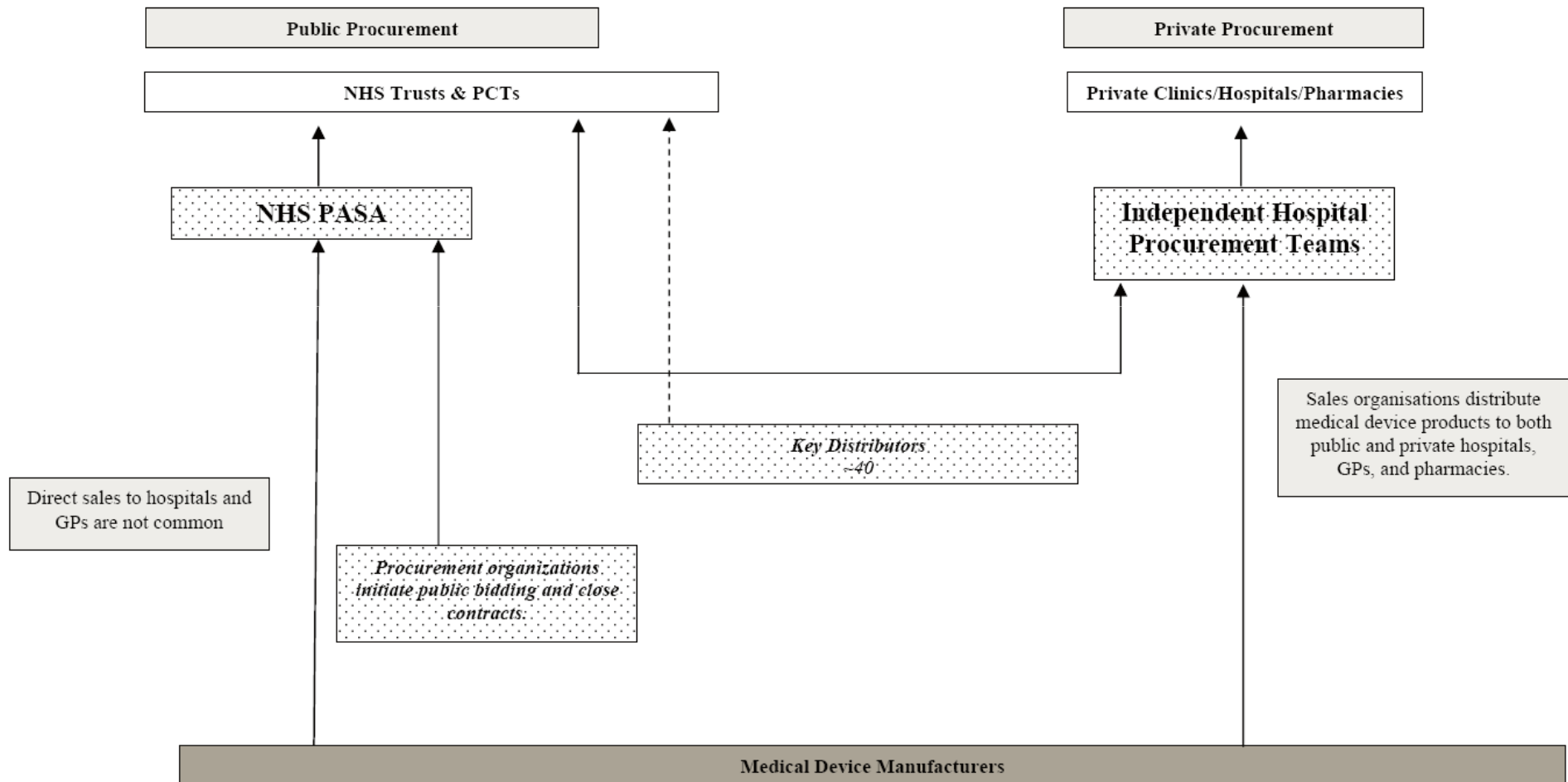
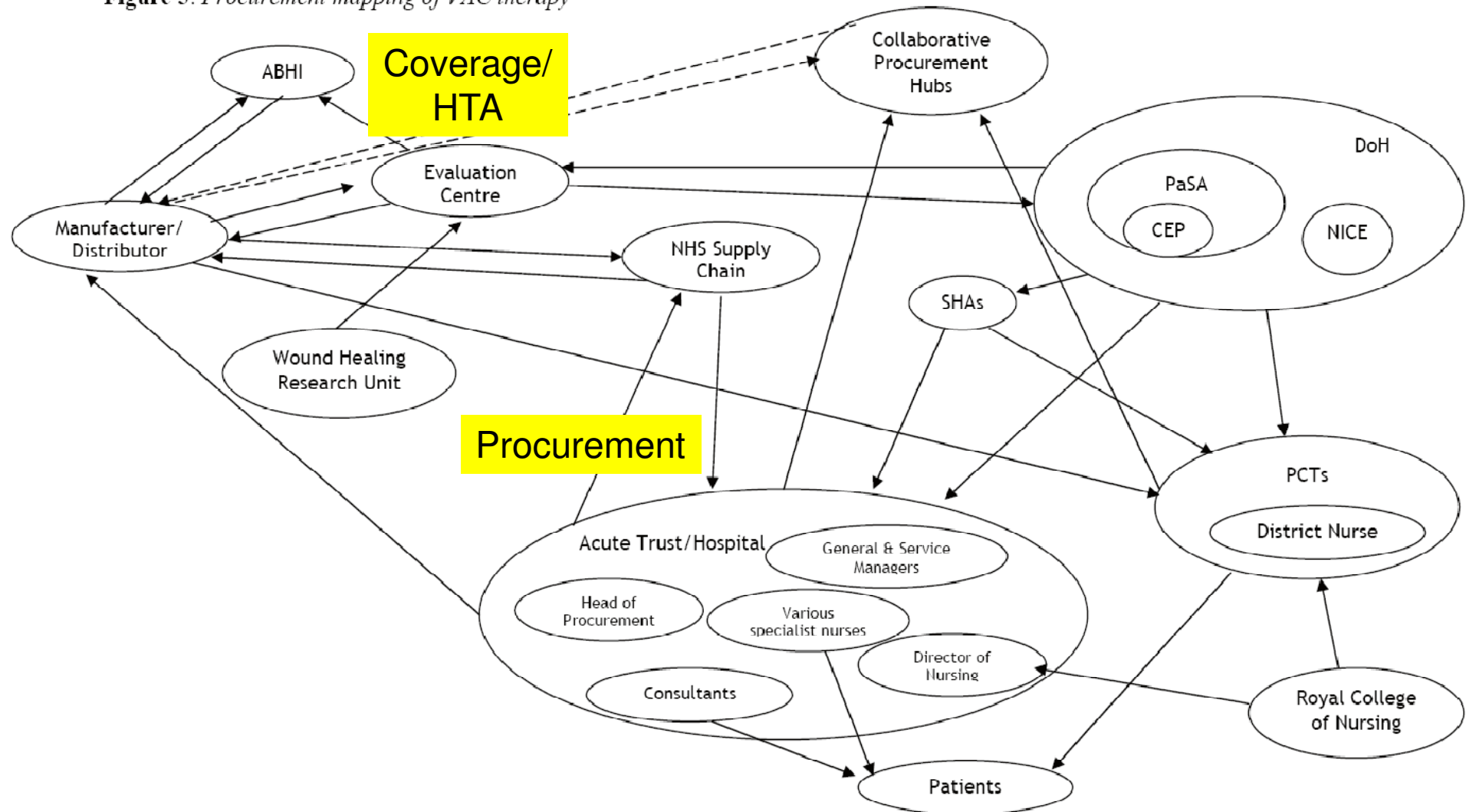


Figure 5: Procurement mapping of VAC therapy



Purchasing/ procurement developments for medical device technologies

- Individual purchasing the rule (but with hospital groups gaining power): **France, Germany**
- From national to coordinated group purchasing: **UK**
- Mixture of individual and regional purchasing with national regulation (RPs! – *but different type*): **Italy**

In conclusion ...

- knowing about the limitations of this analysis
- we need to develop/ use common framework to understand what we are talking about when using the same terms
- collect data on effects on patient outcomes, diffusion of innovation, costs ...
- have a dia- or rather triologue (academics/ industry/ politicians)