Conditional pricing / reimbursement in Italy

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Pharmaceutical policy in Italy

Main aspects

- Unique drugs agency at the central level (AIFA)
- Drugs budget (retail and hospital)
- Regionalisation (Regions have been laso increasing their regulatory power on drugs)
- Ex factory prices and reimbursement simultaneously negotiated: innovativeness (therapeutic target, available treatments, added value), prices in other countries, impact on drugs budget are the main criteria

Pharmaceutical policy in Italy

Main aspects

- AIFA prefers to acting on price than on reimbursement (most of drugs with MA is approved by AIFA)

- Conditional reimbursement / prices have been introduced since 2006 (14 molecules and 15 agreements have been signed so far)

Debate on HTA (Economic evaluation)

•Industry is invited to present a pharmacoeconomic dossier for innovative and orphan drug, but dossier has been neglected by AIFA

•AIFA does not perform economic evaluation: an HTA unit has been recently introduced

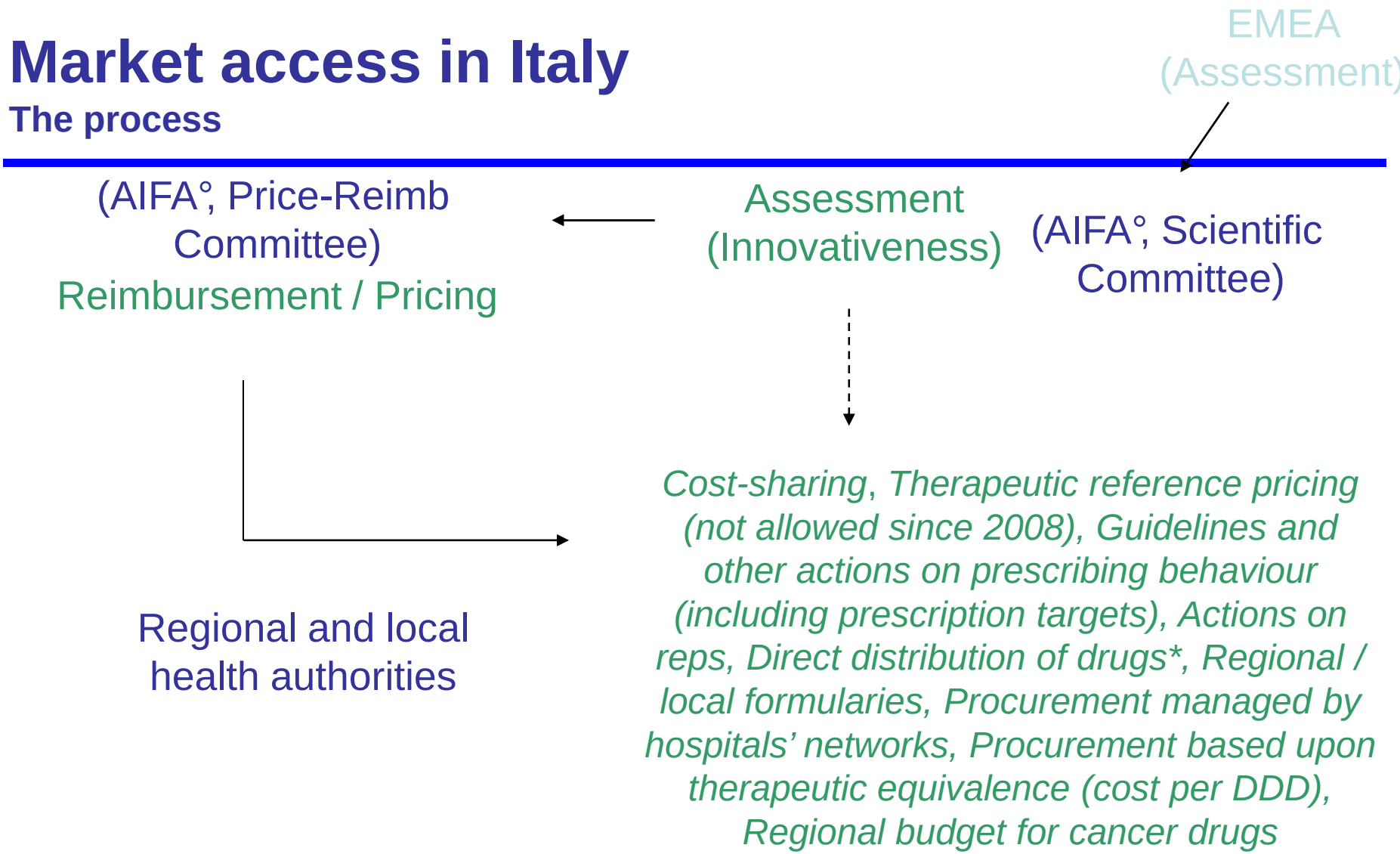
•Some regions have implemented their own HTA programmes

•Many regional and local drug committees advocate a major use of cost/effectiveness at the central / regional / local levels (but in practice they use cost per DDD / therapeutic cycle to define local formularies, organise public tender and govern prescribing behaviour)

•The Italian Association of Health Economics (AIES) has recently (http://www.aiesweb.it/) issued guidelines for economic evaluation studies, addressed to regulatory authorities

Market access in Italy

The process

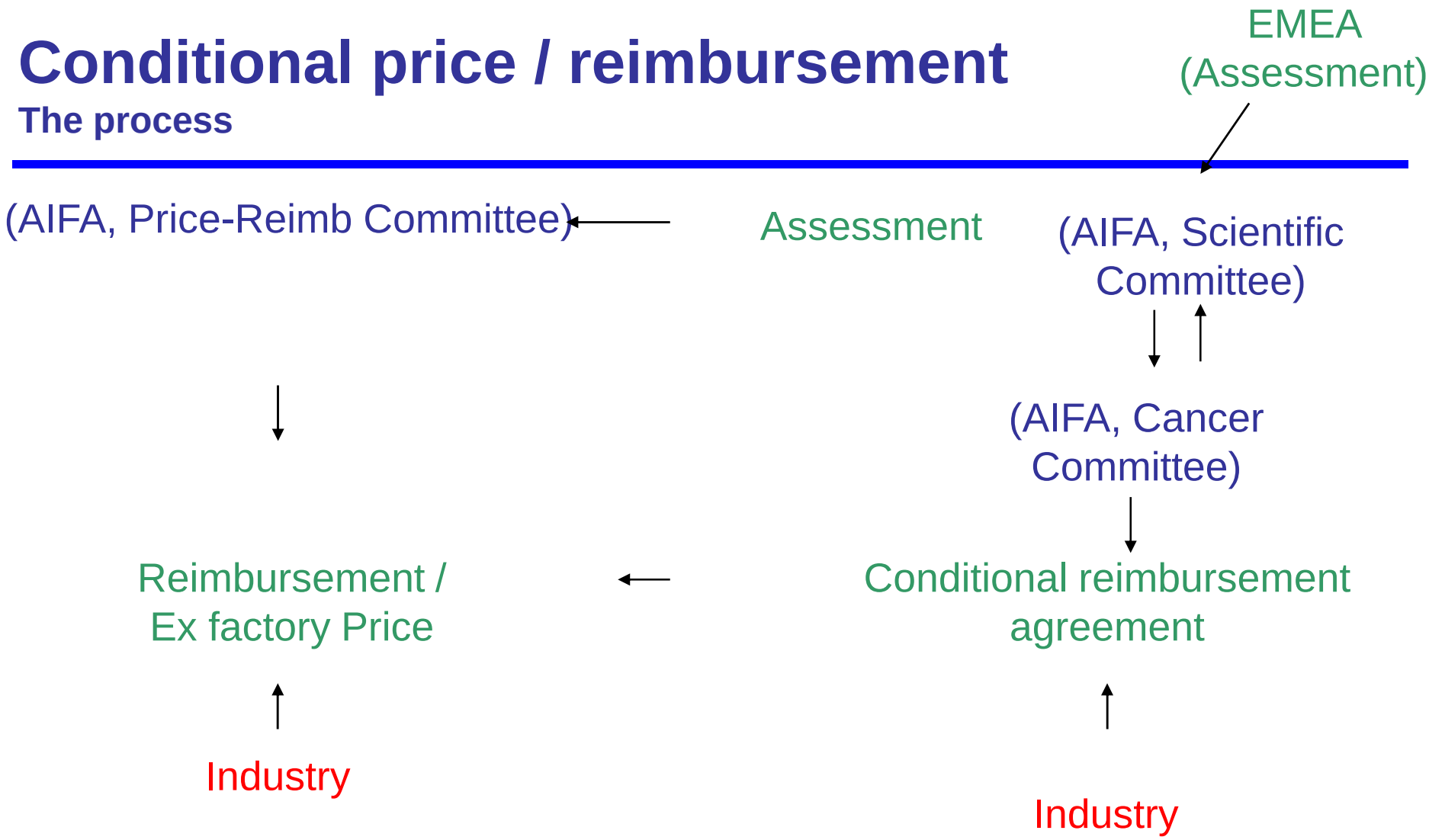


°Agenzia Italiana del Farmaco. The two committees i nclude regional experts

* Direct Distribution (DD) stands for distribution of drugs by hospitals not used in hospital settings - by health authorities (most of these drugs are classified as A – Retail – but are included into a DD National List – possibly modified by Regions – named PHT)

Conditional price / reimbursement

The process



Conditional price / reimbursement

Which kind of agreements?

- Cost-sharing for the first treatment cycles / months
- Risk-sharing: 50% of the price is reimbursed by the industry for non-responders
- Payment for performance: 100% of the price is reimbursed by the industry for non-responders

Conditional price / reimbursement

Present agreements

Molecule	Indication	Date	Type	Agreemeent	Discount
Erlotinib	Advanced metastatic NSCLC M+	July 2006	Cost sharing	50%, 2 first months and 2 first therapeutic cycles	
Sunitinib	Advanced gastrointestinal stromal tumor (II Line)				3.4%
	Advanced a/o metastatic Renal Cancer	November 2006	Cost sharing	50%, 3 first months and 3 first therapeutic cycles	
Sorafenib	Advanced renal cell carcinoma (II Line)	November 2006	Cost sharing	50%, 3 first months and 3 first therapeutic cycles	
	Liver cancer	June 2008	Payment by result	After 2 months, full price for non responders	
Dasatinib	Chronic Mieloid Leukemia (II Line) Acute lymphoblastic leukemia	May 2007	Payment by result	Full price, after 1 months, if no evidence of cytogenetic response progression	7%
Nilotinib	Philadelphia chromosome-positive chronic mieloid leukemia	August 2008	Paymente by result	Full price, after 1 months for non responders	7.1%
Bevacizumab	Metastatic colon rectal cancer	June 2008	Cost sharing / Risk-sharing	50% of the price after 6 treatment weeks For responders: full price after 15 cycles (10/mg per Kg each 2 weeks) or 11 cycles (15 mg per Kg each 3 weeks)	
	Metastatic breast cancer				
	Advanced, metastatic, inoperable non-squamous NSCLC				
	Advanced a/o metastatic Renal Cancer				

Conditional price / reimbursement

Present agreements

Molecule	Indication	Date	Type	Agreemeent	Discount
Lenalidomide	Multiple mieloma (II Line)	February 2008	Cost sharing	50%, 2 first therapeutic cycles	2%
Temsirolimus	Advanced renal cell carcinoma, with at least three risk factors	October 2008	Payment by result	Full price after 2 months for non responders	10%
Panitumumab	Metastatic colon rectal cancer (II Line), EGRF, wild-type KRAS	January 2009	Risk sharing	50% after 2 months for non responders	
Trabectedina	Advanced soft tissue sarcome (II Line)	January 2009	Payment by result	Full price after 4 therapeutic cycles for non responders	
Lapatinib	Advanced or metastatic cancer drugs (HER2+)	May 2009	Payment by result	Full price after 2 therapeutic cycles (6 weeks) for non responders	
Cetuximab	Metastatic colon rectal cancer (II Line), EGRF+, wild-type KRAS (II	June 2009	Risk sharing	50% after 2 months for non responders	5%
	Advanced squamous head carcinoma				
Bortezomib	Multiple mieloma (II Line)	July 2009	Cost sharing	50% for the first cycle (6 weeks of treatment)	14.2%
	Advanced multiple mieloma, already subjetc to bone				
Talidomide	Multiple mieloma (65)				27%
Permetrexed	Non operable malignant mesotelioma				19%
	Advanced or metastatic, inoperable non-squamous NSCLC				
Nelarabina	T-All cella Acute lymphoblastic leukemia				10%
	T-Lbl cell lymphoblastic lynfoma (II Line)				

Conditional price / reimbursement

Which impact?*

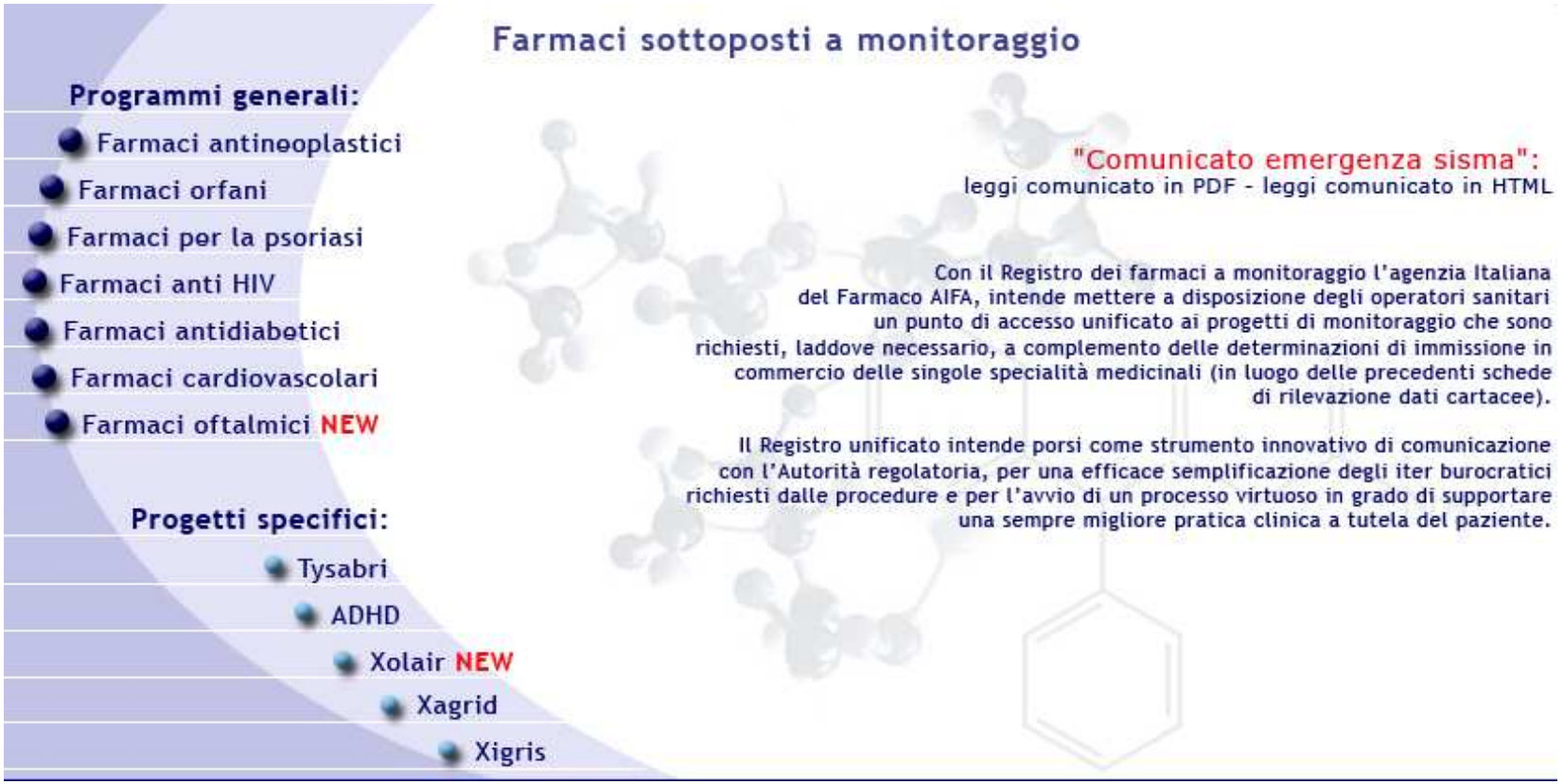
Molecule	Years	Indication	Agreement	Patients	% non responders	Savings
Erlotinib	2007-(2009)	Advanced metastatic NSCLC M+	Cost-sharing	52	51,9%	20,5%
Sorafenib	2007-(2009)	Advanced renal cell carcinoma (II Line)	Cost-sharing	30	53,3%	34,6%
		Liver cancer	Payment by result	44	72,7%	45,9%
Sunitinib	2007-(2009)	Advanced a/o metastatic Renal Cancer	Cost-sharing	39	35,9%	22,1%
Bevacizumab	2005-(2009)	Metastatic colon rectal cancer	Cost-sharing / Risk sharing	144	41,7%	21,5%

*** Veneto Region (4.8 million inhabitants). National data (Aifa) are not available**

Drug monitoring registry

Anti-cancer drugs registry (Aifa, 2006)

Other drug monitoring registry



Drug monitoring registry

Which data?

			Cause di fine trattamento				
Farmaci oncologici	N. Pazienti in trattamento*	Pazienti con fine trattamento (% su trattati)	Fine del trattamento per decisione clinica	Progressione	Morte	Tossicità	Altro
AVASTIN® (27/03/2006)	1967	481 (24.5)	98	241	26	53	63
ELOXATIN® (27/03/2006)	2818	1127 (40.0)	683	44	5	299	96
ERBITUX® (27/03/2006)	1711	714 (41.7)	53	525	43	52	41
FASLODEX® (27/03/2006)	2853	778 (27.3)	4	654	66	16	38
FOSCAN® (27/03/2006)	22	4 (18.1)	0	2	2	0	0
GLIADEL® (27/03/2006)	130	44 (33.8)	27	3	4	0	10
ZEVALIN® (27/03/2006)	184	51 (27.7)	47	0	0	0	4
TARCEVA® (02/08/2006)	3338	1040 (31.2)	5	603	265	73	94
HERCEPTIN® (27/10/2006)	2156	144 (6.7)	79	14	0	38	13
NEXAVAR® (21/12/2006)	662	128 (19.3)	0	55	21	31	21
SUTENT® (21/12/2006)	797	117 (14.7)	0	41	28	23	25
SPRYCEL® (04/06/2007)	172	5 (2.9)	1	0	3	0	1

Source: Aifa, 2008

Conditional price / reimbursement

Which problems

- Not easy to detect non-responders
- Transparency (agreements are not published)
- Difficult to manage at the local level
- Is homogeneously applied?
- How agreements (cost-sharing, risk-sharing, payment by result) are chosen?

Thank you

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