# Innovative Access Solutions

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# Disclaimer

This presentation reflects my own views, in particular, on possible access solutions for medicines and does not reflect the views of the government or any other organization or committee that I am affiliated with.

# Outline

- ICON's approach
- Funding models
  - Patient access programmes
  - Risk sharing schemes
  - Outcomes models
  - Personalised medicines
  - Other models
- International experience
- Closing remarks

# Just to be sure!

Presentation is about

RE-IMBURSEMENT

and NOT about

PRICING

# Differential Pricing

Adapting drug prices to the purchasing power of consumers in different geographical or socio-economic segments could potentially be a very effective way to improve access to medicines for people living in low and middle-income countries.

Yadav, P (2010), Differential Pricing for pharmaceuticals

# ICON's approach

- Cost awareness
- Costing of clinical protocols
- Funding by treatment intent
- Clinical pathways
- Multidisciplinary teams
- Rational use of medicines - EBM
- Pharmaco-economic evaluation

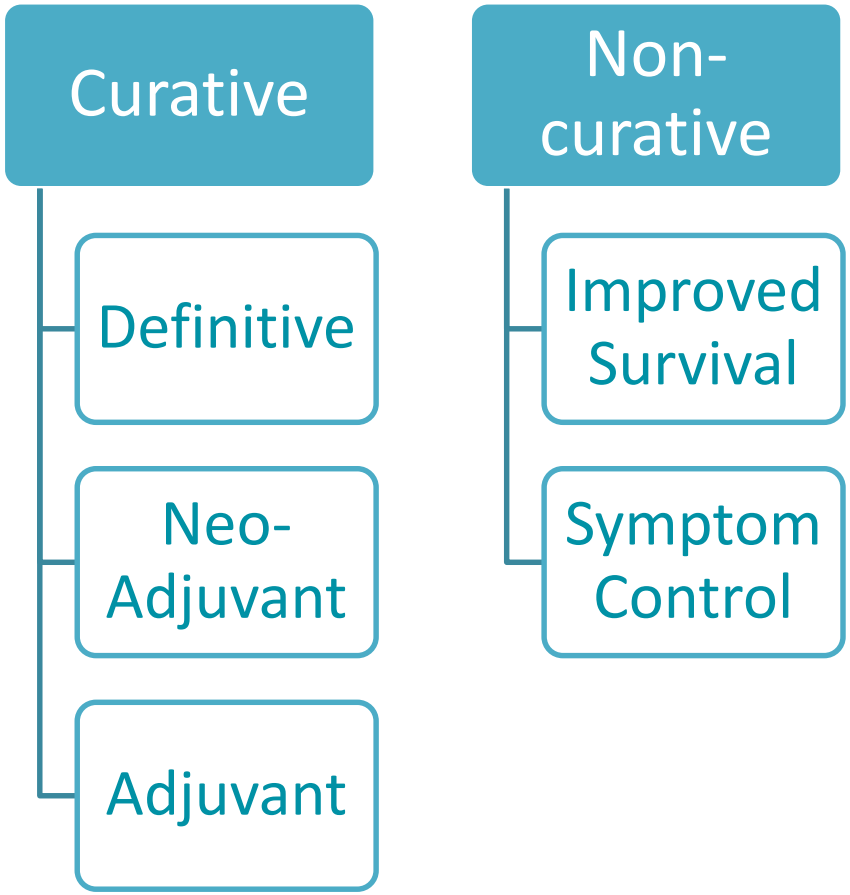
# Drug costs for breast cancer curative intent- adjuvant - standard

| | Total cost | Tariff cost | Drug cost | Utilization |
|---|---|---|---|---|
| AC (4) | **R 16,534** | R 12,656 | R 3,878 | 14.4% |
| Classic CMF (6) | **R 41,951** | R 37,968 | R 3,983 | 6.2% |
| TC (4) | **R 46,027** | R 12,656 | R 33,371 | 4.9% |
| FEC100 (6) | **R 31,482** | R 18,984 | R 12,498 | 9.6% |
| AC(4) + doce(4) | **R 69, 318** | R 25, 312 | R 44, 006 | 19.5% |
| AC(4) + pacli weekly (12) | **R 74,764** | R 50,624 | R 24,140 | 30.8% |
| FEC 100(3) + doce(3) | **R 55,329** | R 18,984 | R 36,345 | 5.2% |
| FEC600/90/600(4)+ pacli weekly(8) | **R 59,810** | R 37,968 | R 21,842 | 0.42% |
| Doce (3)<br>Trastuzumab(9)<br>FEC(3) | **R160,082** | R 28,476 | R 31,606<br>R 97,164<br>R 4,346<br>R 131 606 | 57.1% of Trastuzumab containing regimens |

# Drug costs for breast cancer curative intent - adjuvant – enhanced

| | Total cost | Tariff cost | Drug cost | Utilization |
|---|---|---|---|---|
| Trastuzumab (18) | R 397,722 | R 57,647 | R 340,075 | 39.3% |
| Carbo/doce( 6)<br>Trastuzumab (6) | R249,168 | R 20,346 | R 58,784<br>R170,038 | 3.6% |

# Protocols driven by treatment intent



# CLINICAL PATHWAYS

Clinical pathways are detailed, evidence-based processes for delivering cancer care for specific patient presentations, including the state and stage of disease. A regimen for treatment is specified, including the names of the drugs, dosing levels, and schedule for administration. Pathway users say that pathways reduce errors, reduce costs, and increase efficiency.

# RATIONAL USE OF MEDICINES

Cost-effective medicines become cost-ineffective if used irrationally.

# RATIONAL USE OF MEDICINES

Some approaches to improve the rational use of medicines:

- Evidence-based medicine
- Cost-effectiveness
- Clinical pathways
- Multi-disciplinary teams
- Centres of excellence

# Funding models

- Price volume arrangements
- Patient access programmes (free drugs)
- Risk sharing schemes
- Why are these models not applied extensively in the private sector in SA?

# Patient access programmes

Would you like to obtain free medicines now and in the future in the public and private sector?

# Patient access programmes

Would you like to obtain free medicines under the current system in the private sector?

# Patient access programmes

Formation of charitable programmes or trusts.

- Cover co-pays
- Free medicines

# Patient access programme

Price /utilization capping:

- Free initiation of therapy
- costs covered by pharma if an accumulated dose is exceeded
- costs covered by pharma if certain number of cycles are exceeded
- additional medicines at no costs or a large discount is provided by pharma if a payer's budget is exceeded

# Risk sharing

- Value-based pricing
- Conditional coverage
- Conditional re-imbursement
- Coverage with evidence
- No cure no pay
- Health impact guarantee
- Outcomes guarantee
- Performance-based re-imbursement

# Risk sharing schemes

A risk-sharing agreement is a tool for manufacturers of biological medicines and payers to manage the risk of introducing clinically effective and very expensive medicines into the healthcare market.

Risk-sharing agreements are particularly useful for costly drugs that have some degree of uncertainty associated with their clinical outcomes, and spread the risk between pharma and the payer.

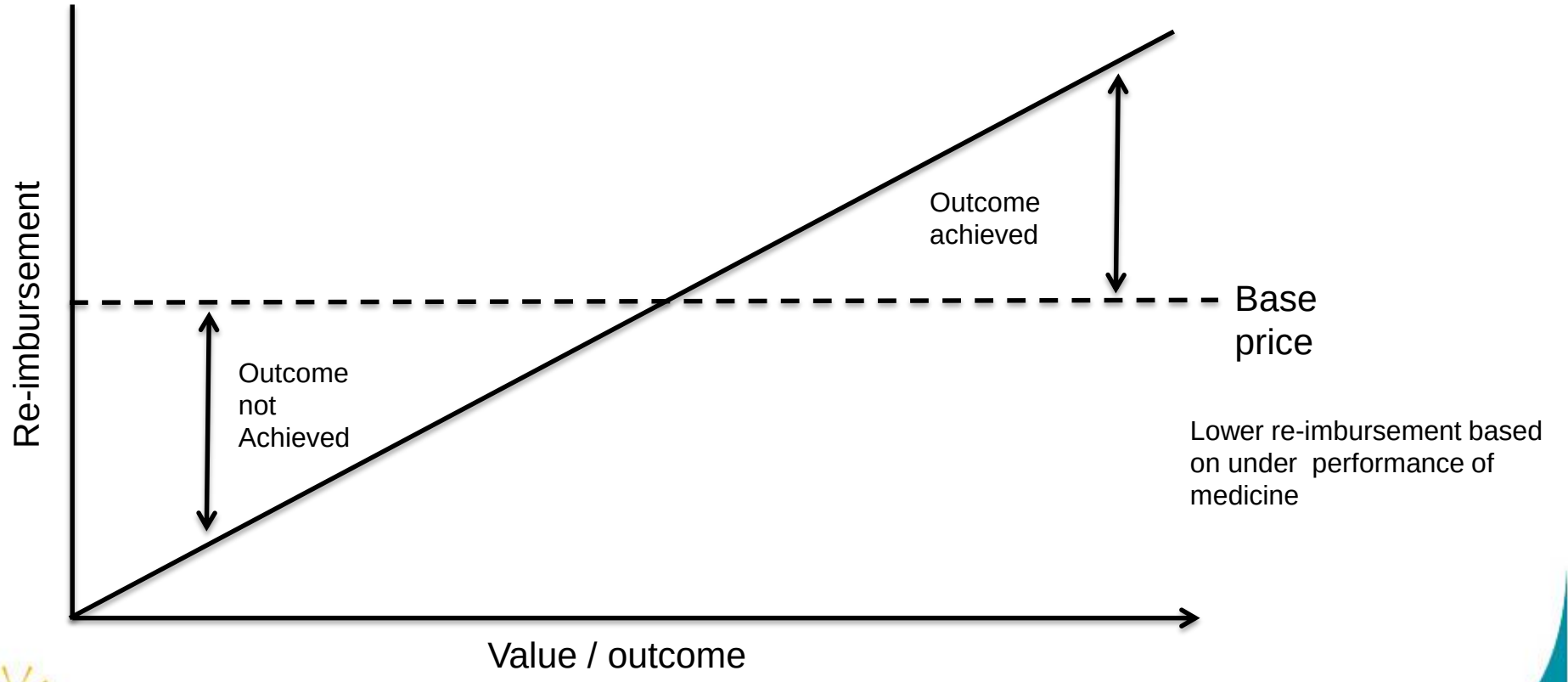
Process by which two parties or more agree to share the risks associated with achieving a certain outcome.

# Risk sharing schemes

- Financial based
  - price-volume arrangements / budget impact scheme
  - Based on payback mechanism

- outcomes/performance-based

# Outcomes-based re-imbursement

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# Pros: outcomes-based model

- Improve access to new, innovative drugs
- Outcomes-based approach
- Localised cost-effective targets
- Build clinical experience with medicines
- Opportunities for partnership

# Barriers: outcomes-based model

- SEP at launch could be set higher to compensate for risk
- early access to new medicines with as yet unproven efficacy and safety
- Funders may be funding an appreciable proportion of new drug's development costs
- Should not be a substitute for good clinical trials

# Barriers: outcomes-based model

- specific objective outcomes for clinical measures not always in place.
- validated measurement tools
- burdensome administration (high costs)
- rules and conditions to participating providers
- ethics and confidentiality issues
- cost of managing therapeutic failures

# Selection of medicines for outcomes-based model

**Criteria**:

- simple value-metrics to measure outcomes
- clearly defined outcomes
- medicines with high budget impact
- well-defined treatment population
- well-defined treatment duration

# Re-imbursement linked to benefits

Develop affordable benchmark for medicines per disease

Determine total costs as a reasonable cost for the treatment of a specific disease per year:

| | | |
|---|---|---|
| Lab tests | Facility | Doctor |
| **Medicines** | Hospital | |
| Nursing | | |

Determine a benchmark for medicine costs  for the disease.

Determine a benchmark for medicine costs for the medical scheme benefit.

# Personalised medicines

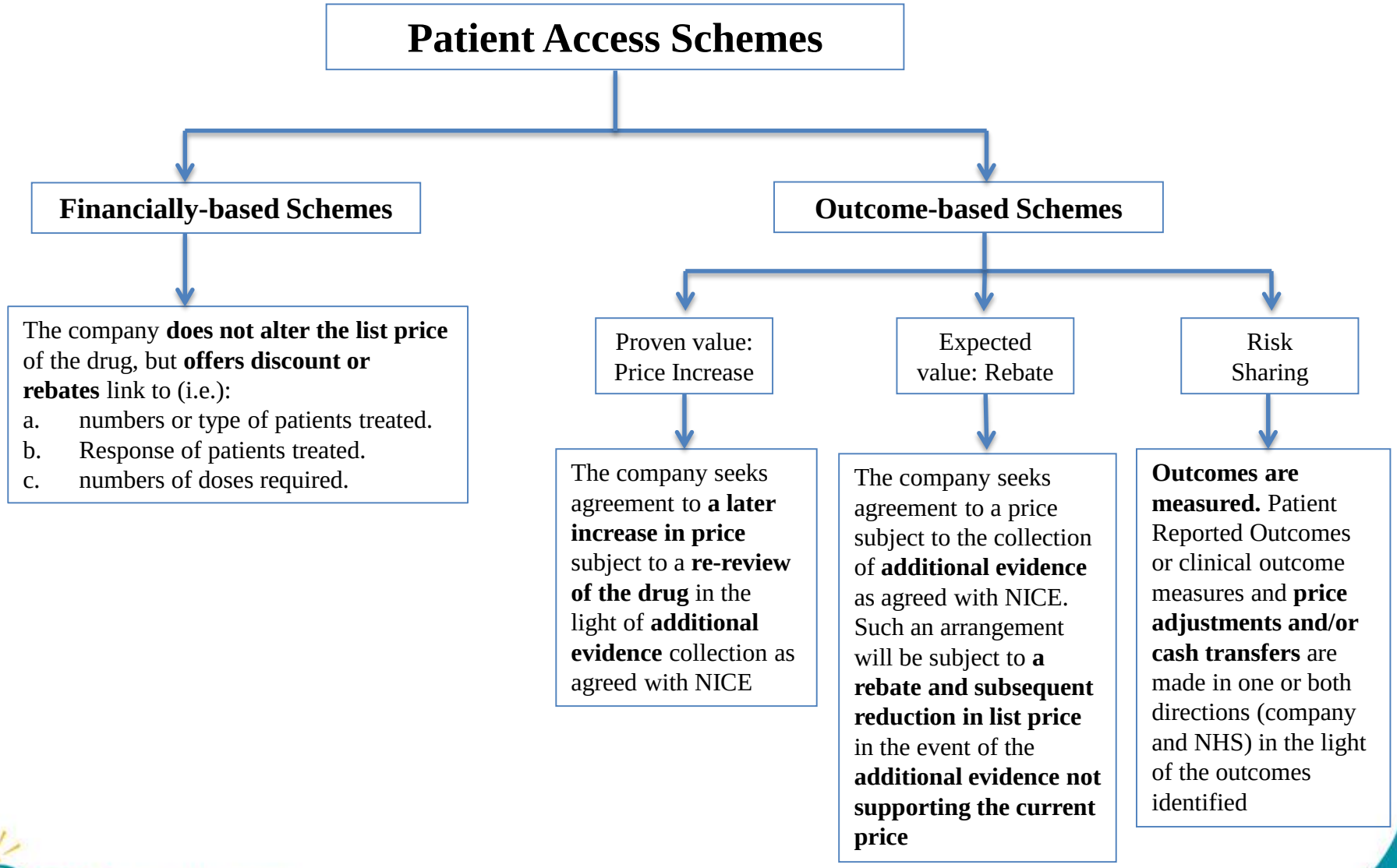
- re-imbursement linked to genetic testing
- medicines can be tailored to specific cancers depending on molecular aberrations

# Other funding considerations

- Re-imbursement based on budget impact
- Pharmacoeconomic evaluation
- Carved out benefit for biologicals
- Vial sharing

# International experience

# Patient Access Schemes in the UK

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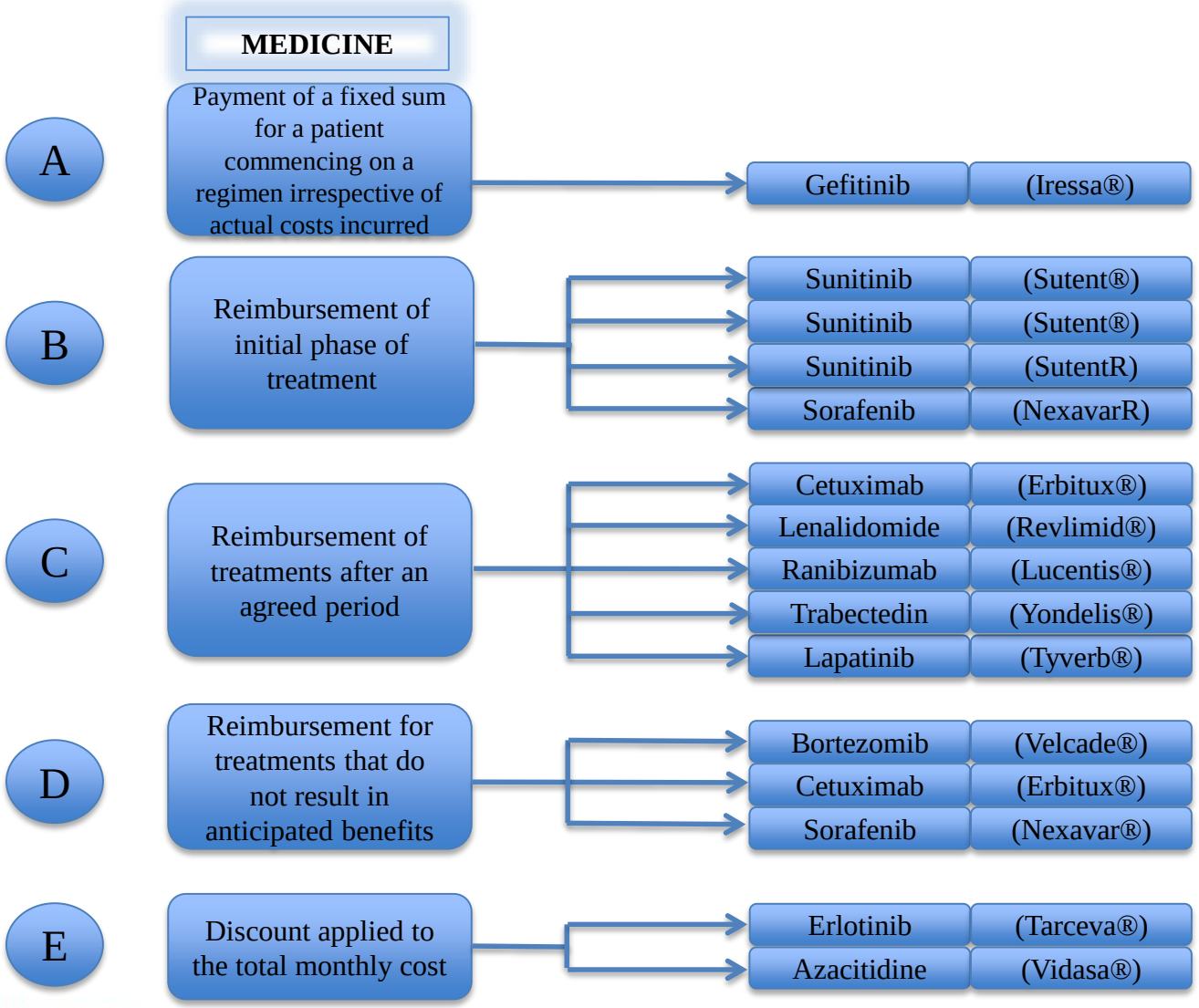
**Source:** Pharmaceutical Price Regulation Scheme (PPRS) 2009

# Oncology Patient Access Schemes in the UK




**Source:** EMINet's compilation based on NHS Davon (http://www.devonpct.nhs.uk/)

# Financial Agreements in Portugal for Hospital Oncology Medicines

| Brand Name | Active Ingredient |
|---|---|
| Sprycel | Dasatinib |
| Nexavar | Sorafenib |
| Revlimid | Lenalidomide |
| Lucrin Depot | Leuprorreline |
| Keloda | Capecitabine |
| Yolendis | Trabectadine |
| Litak | Cladribine |
| Vectibix | Panitumumab |
| Torisel | Temsirolimos |
| Evoltra | Clofarabine |

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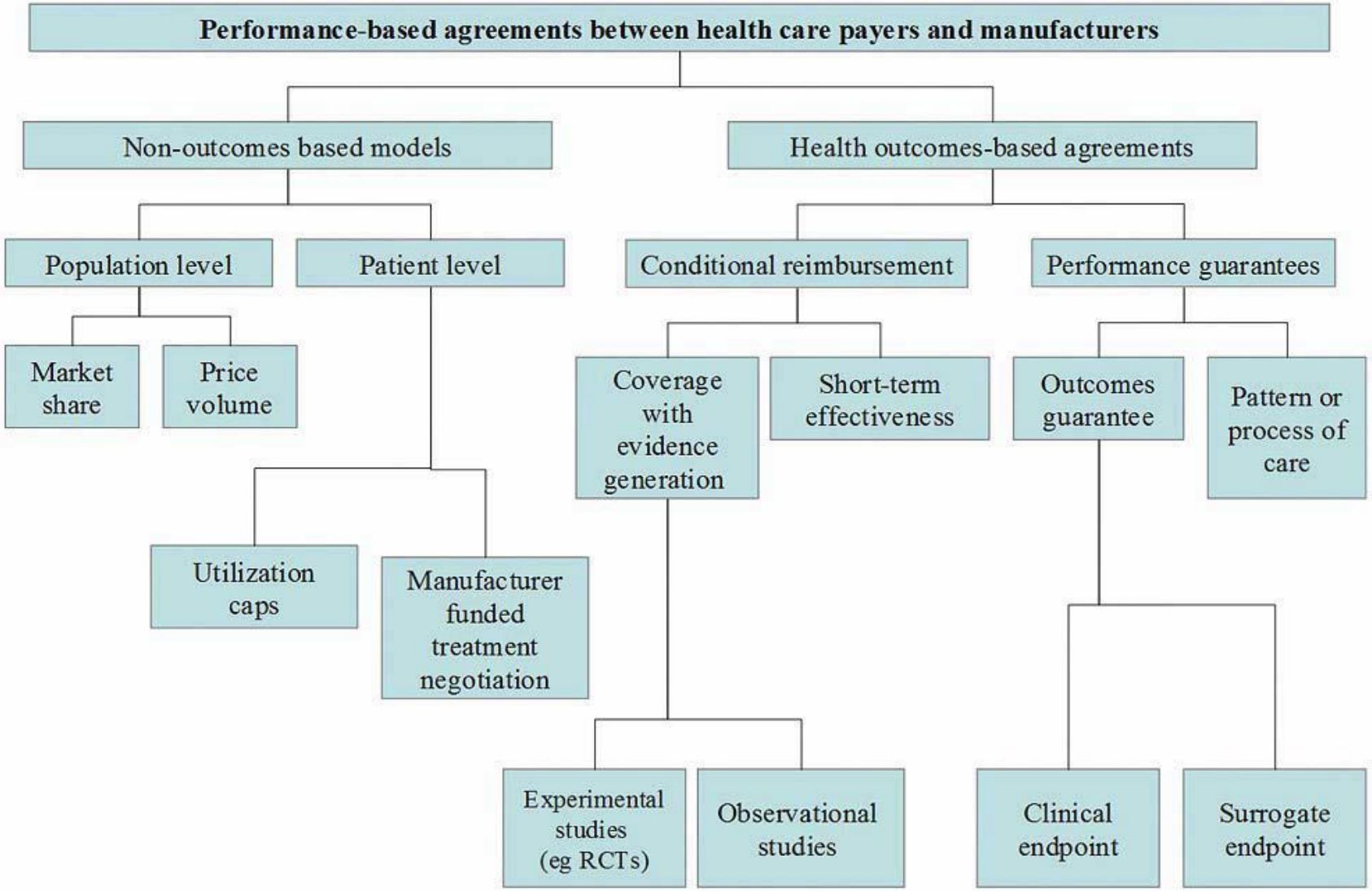
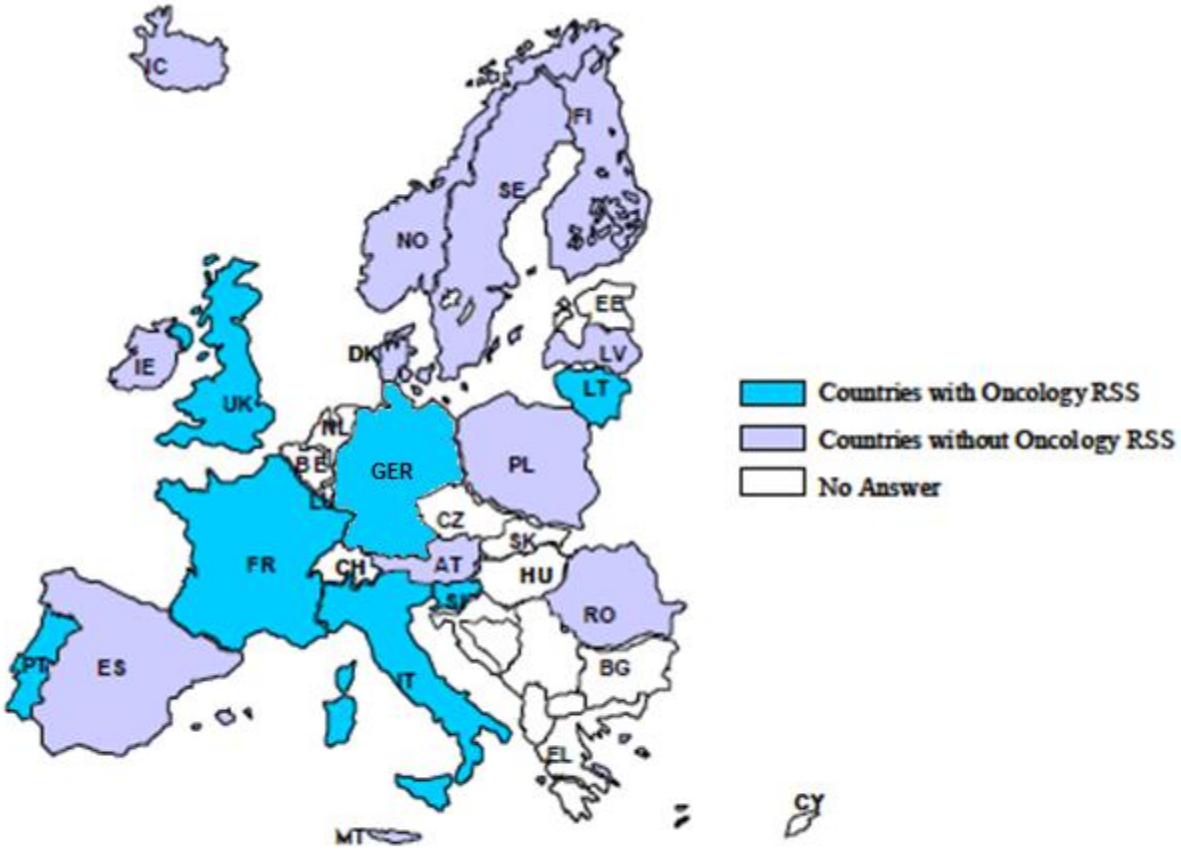
**Source:** Infarmed (National Authority of Medicines and Health Products) – Ministry of Health (Portugal)






**Source:** IMS Pharma Pricing & Reimbursement - 2009

# Answers to the Online Survey




Source: EMINet online survey on RSS

# Innovative Access Schemes in Italy for Oncology Medicines

| Payment by results | Cost Sharing Scheme | Risk Sharing Scheme |
|---|---|---|
| Dasatinib (Leukemia) – 2007<br>Nilotinib (Leukemia) – 2008<br>Temsirolimus (RCC) – 2008<br>Sorafenib (HCC) – 2008<br>Pegaptanib (AMD) – 2009<br>Ranibizumab (AMD) – 2009<br>Trabectedin (STS) – 2009<br>Lapatinib (mBC) – 2009 | Erlotinib (NSCLC) – 2006<br>Sunitinib (RCC) – 2006<br>Sorafenib (RCC) – 2006<br>Bevacizumab – 2008<br>Bortezomib (Myeloma) – 2009 | Panitumumab (mCRC) – 2009<br>Cetuximab (CRC) – 2009 |

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**Source:** Compilation by the authors based on EMINet survey, literature review and presentations

# Description of RSS in Italy

| Active Ingredient | Description | Date |
|---|---|---|
| Bortezomib | Cost-sharing scheme that requires manufacturers to pay back 50% of the treatment cost for all eligible patients during the first treatment. | 2009-2011 |
| Erlotinib | 50% price reduction for the first two cycles of therapy. | 2006-2011 |
| Nilotinib | Manufacturers must assume all costs for the first month of treatment for non-responder patients. | 2008-2011 |
| Panitumumab | Risk sharing scheme that requires the manufacturer to pay-back 50% of the cost for non-responders (evaluation after 2 months of treatment). | 2008-2011 |
| Sorafenib | Treatment of advanced renal cell carcinoma: Risk sharing consisting of a 50% price reduction for the first 3 months of treatment.<br>Treatment of hepatocellular carcinoma: Full price reduction for the first 2 months of treatment. Later reimbursed through credit notes for non-responders. | 2009-2011 |
| Sunitinib | 50% price reduction for the first months of treatment. | 2006-2011 |
| Temsirolimus | The medicine is freely provided by the manufacturer for the first two months of treatment but only for non-responders. | 2008-2011 |



**Source:** AIFA (Italian Medicines Agency) – Ministry of Health

# Number of treated patient and causes for stop the treatment for some oncology drugs. Italy 2007

| | | | Causes of stopping the treatment | | | | |
|---|---|---|---|---|---|---|---|
| **Oncology medicines** | **Number of treated patients** | **Patients that have finalised the treatment (%)** | **Stopping the treatment by clinical decision** | **Progression** | **Death** | **Toxicity** | **Other** |
| AVASTIN® | 1967 | 481 (24.5) | 98 | 241 | 26 | 53 | 63 |
| ELOXATIN® | 2818 | 1127 (40.0) | 683 | 44 | 5 | 299 | 96 |
| ERBITUX® | 1711 | 714 (41.7) | 53 | 525 | 43 | 52 | 41 |
| FASLODEX® | 2853 | 778 (27.3) | 4 | 654 | 66 | 16 | 38 |
| GLIADEL® | 130 | 44 (33.8) | 27 | 3 | 4 | 0 | 10 |
| ZEVALIN® | 184 | 51 (27.7) | 47 | 0 | 0 | 0 | 4 |
| TARCEVA® | 3338 | 1040 (31.2) | 5 | 603 | 265 | 73 | 94 |
| HERCEPTIN® | 2156 | 144 (6.7) | 79 | 14 | 0 | 38 | 13 |
| NEXAVAR® | 662 | 128 (19.3) | 0 | 55 | 21 | 31 | 21 |
| SUTENT® | 797 | 117 (14.7) | 0 | 41 | 28 | 23 | 25 |
| SPRYCEL® | 172 | 5 (2.9) | 1 | 0 | 3 | 0 | 1 |

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**Source:** Aifa. Registro Farmaci Cncologici Sottoposti a Monitoraggio Rapporto Nazionale 2007

# Closing remarks

Provide patients with some hope of gaining access to the newest therapies.

Some funding models could be implemented in a strictly controlled environment.

Irrational use of medicines

- Evidence-based medicine
- Clinical pathways
- Centres of excellence
- Multi-disciplinary teams
- Treatment plans / discharge plans