

*“Is value-based care in Europe here to stay?
Healthcare reforms and Companies strategies”*

Prof. Fabrizio Gianfrate
Health Economics and Mkt Access
Italy

Health Daily
Pricing & Reimbursement Conference
Athens 30th June 2016

Governments' main tool for managing public pharma expenditure



Sustainability during the last years.

Generics

Few new drugs

Pricing cut

- decreases

- formularies

- distribution processes and margins

- financial based agreements (price-volumes, etc.)

- outcome based agreement (risk sharing/payment by results, etc.)

- ...

Budget caps (product, categories, companies) and payback

Regional/Local access restrictions

Finding out resources for pharma

Resources

- Shift from other welfare budgets
- Shift from other NHS budgets
- Regional/local devolution
- Copayment increasing

Price set-up

- Reference price
- Commodities

Delisting

- Ethical choices

Volumes

- Patients' sub-population restrictions at Mkt access
- Payment by result – Risk Sharing agreement schemes

Caps and Paybacks

- National expenditure
- Per therapeutic area
- Per single product
- Cost per Qaly thresholds

Volumes restrictions

Difficulties to lower the price

- Unsuccessful negotiation

- Parallel trade

High price but reducing volumes narrowing reimbursed indications

- Restriction to reimbursement on indications

- Biomarkers

- Mkt access limited to patient subgroups by several criteria

Payment by result-Risk sharing

Volumes: Payment by Result – Risk Sharing

- Tradizional model:

Payer buys a probability of therapeutic success

- Payment by Result – Risk Sharing model

Payer buys an acquired therapeutic success

Level of negotiated price has to be different

Caps and paybacks

National/local level

Therapeutic area

Single product

Payback → a number of patients is treated in charge of manufacturers

Delisting

Delisting “mass mkt” drugs” (antihypertensives, pertensivi, PPIs, statins, antibiotics, etc.)

Average of payment for “mass mkt” drugs 0,2 €/daily

Private payment only over an income threshold

10%-20% of resources available to be addressed to innovative drugs, premium prices, etc.

Ethical problems?

Price set-up

Classic model: based on COGS

“Industrial value”-> commodity →

“Marginalist model”: patient/community value benefit

“patients/community value”-> therapeutic and economic benefit

“Mass mkt” and “innovative” drugs: same criteria for pricing does make still sense?



0,2 €/day



800 €/day

Marginalist model

Which threshold as cost-opportunity ($xx.xxx \text{ €} \times \text{QALY}$)?

Who can assess the value and the respective price and on which basis?

Marginalist model: Utility assessment and value

- Assessment

Rating Scale

Time Trade Off

Standard Gamble

- Value

Willingness to Pay

Human Capital

Wide standard deviation (rich vs poor, old vs. young, optimistic vs. pessimistic, etc.)

Marginalist model: cost x Qaly - wide SD



Product Value Assessment Dossier

Show economic value at national and local level

- Cost effectiveness/cost utility/cost benefit
- Budget Impact
- Outcome Research
- HTA
- HrQoL
- ---

Identify right costs on perspective

Identify competitors features to evaluate (SWOT)

Flexibility on local adaptation (local costs and outcomes)

DDD, NNT, etc., etc.

Early access schemes

ATU (FR) – 648, 326, Class Cnn (ITA), EAMS (ENG), Compassionate (EU)

only innovative drugs not (yet) reimbursed (even when restr. indication)
drugs approved abroad - EMA

reimbursed by NHS (ATU, 648, 326) or not reimbursed by NHS (Cnn)
free price by manufacturer
even payed by hospital budget (NHS if public hospital))

Off-label: when no alternative
when alternative but more expensive

Adaptive licensing and reimbursement - PRIME

First indication → first price: on which values?

Following licensing → following prices: on which values?

Changing price during time?

Planning difficulties (NHS and manufacturers)?

Real World Evidences?

Which internal reference price comparison?

Which cross-national reference price comparison if time-shifted?

Prof. Fabrizio Gianfrate

Health Economics

University of Rome, University of Ferrara

E-mail: fabrizio.gianfrate@unife.it
fabrizio.gianfrate@alice.it