National Medicines Management Forum

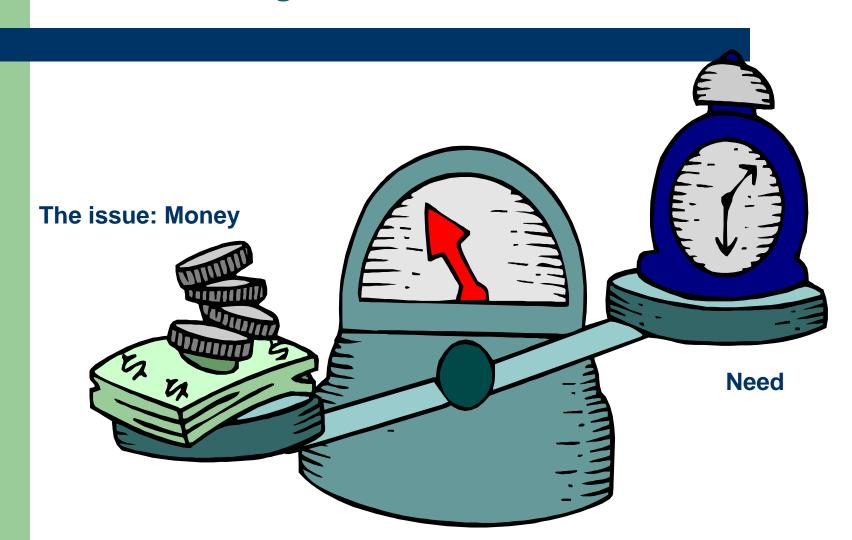
Balancing needs and resources in medicines delivery



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- Availability of resources
- Pharmaceutical pricing & reimbursement policy
- Trends in utilisation of medicines / resources
- Major Challenges
- Demand side measures
- Untapped arenas

Balancing Needs and Resources



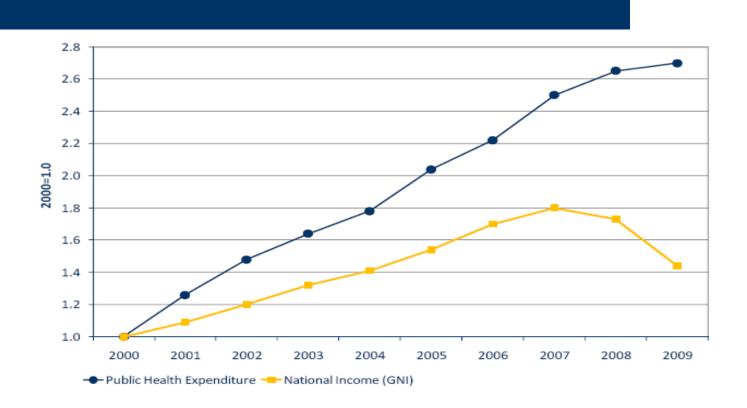
Statutory function: Health Act 2004

"The object of the Executive is to use the resources available to it in the most beneficial, effective and efficient manner to improve, promote and protect the health and welfare of the public"

Section 7(1) of the Health Act 2004



Trends in Public Health: Expenditure & National Income



Ireland - IMF Commitments

- Budget 2011
 - The budget will provide for a reduction of expenditure in 2012 of €2,100m including:
 - Social expenditure reductions
 - Reduction of public service numbers and public service pension adjustments
 - Other programme expenditure, and reductions in capital expenditure

- Budget 2012
 - The budget will provide for a reduction of expenditure in 2013 of no less than €2,000m including:
 - Social expenditure reductions
 - Reduction of public service numbers and public service pension adjustments
 - Other programme expenditure, and reductions in capital expenditure

Suppliers and staff suffer under Spanish budgetary cuts

Patients in Italy face

French budget plan will continue a freeze on new spending in 2012

Medical posts to be slashed and hospitals reorganised in Greek public health sector

Hospitals and local health units of the Portuguese state's enterprise sector have to save €300M more than was originally set for 2012

Germany's Healthcare system
the government has decided to
raise premiums and cut into the
profits of doctors, dentists,
hospitals and pharmaceutical
manufacturers

Faced with a ballooning deficit in

Dutch Cabinet cuts spending in 2011: more to come - include increasing patient health care payments

Cost of employer provided health insurance doubles in US in a decade

Nurses protest at mental health cuts in South London

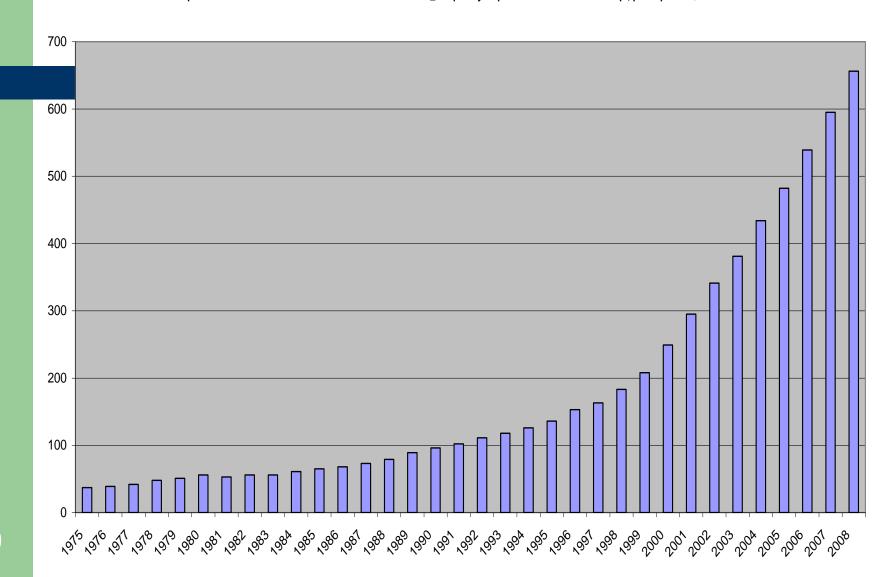
Dutch GPs are set to strike over 10% cuts to primary care budget

Resource Utilisation

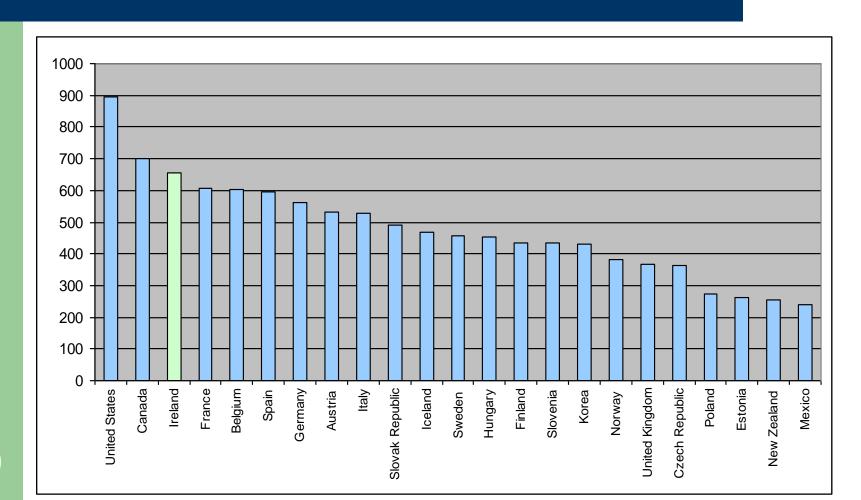
Trends

OECD Pharmaceutical Spending per capita (US\$ PPP)

http://www.irdes.fr/EcoSante/DownLoad/OECDHealthData_FrequentlyRequestedData.xls#'Pharma exp., per capita US\$ PPP'!A1



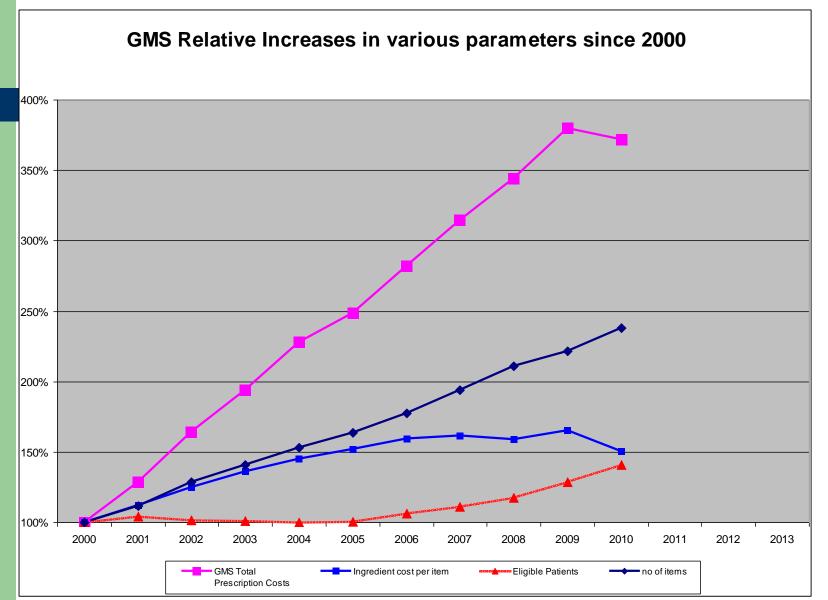
Pharmaceutical expenditure per capita, (US\$ PPP, Year 2008 - OECD June 2010)



Pricing & Reimbursement Policy 2006

- Provide public access to innovative and other medicines through reimbursement based on:
 - continuity and security of supply
 - affordability
 - sustainability
 - value for money
- Limited budget
- Reduce medicines prices to EU average
- 11

Parameter trends (2000 as baseline)



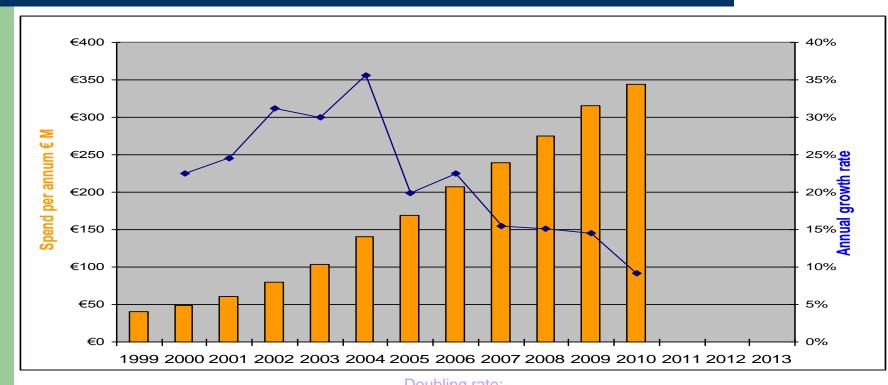
GMS Prescription Costs

Year	2000 – 2005	2005 - 2010
Total prescription costs	2.49 x Increase	1.49 x Increase
Number of items	1.64 x Increase	1.45 x Increase
Average ingredient cost per item	1.52 x Increase	Stabilised
Number of eligible patients	Stable (1% increase)	1.4 x Increase

Estimated that an additional €269M GMS prescription costs would have arisen in 2010 if ingredient cost per item had continued to increase at pre 2005 rates

Number of prescribed items continues to increase: based on 2005 – 2010 rate €100M in extra funding (or alternatively savings) is required every year

High Tech Medicines: Spend per annum & annual growth rates



Doubling rate:

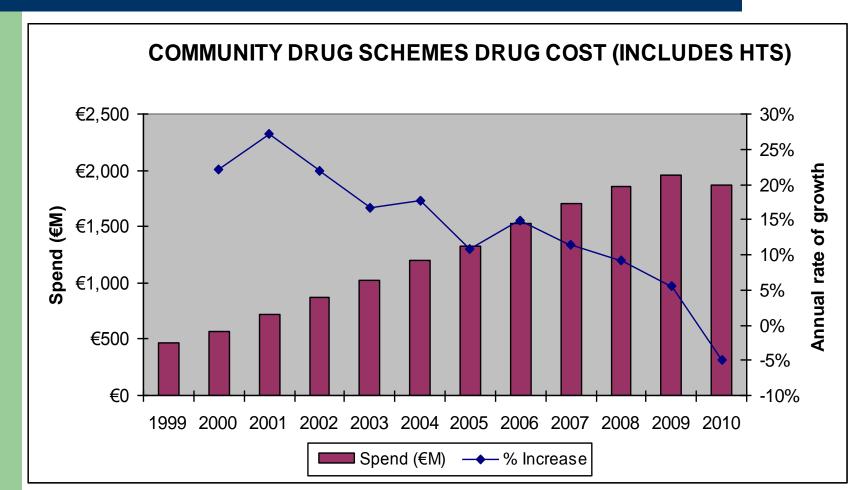
2010 annual rate of growth (9%) – 8 years

2007 – 2009 annual rates of growth (15%) – 5 years

2000 – 2006 annual rates of growth (approx 25%) – 3 years

Overall GMS, DPS, LTI, HiTech (HTS) Prescription costs Cumulative figures for the 4 major schemes

Note:2010 first year to reduce



Major Challenge

New Medicines

- 1. Pricing
- 2. Reimbursement

2006 IPHA Agreement

- Pre-2006 price had been based on the lower of the UK or the average of 5 agreed countries
- Post September 2006: launch price offered on the basis of the average of an extended 9 countries
 - Health Technology Assessment on new (and existing products)
 - "Value Based Pricing"

Pricing applications: Agreed Countries

Austria	Belgium	Denmark
?? Free pricing @ launch	Average of Austria, Denmark, Finland, France, Germany, Greece, Ireland, Italy,	Free pricing @ Launch
Average of Belgium, Bulgaria, Cyprus,	Netherlands, Spain, Sweden, UK at launch	
Czech Republic, Denmark, EE, Finland, France, Germany, Greece, Hungary,		
Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, SK, SI, Spain, Sweden & UK		
Finland	France	Commons
Finiand	France	Germany
Median of Austria, Belgium, Denmark, Greece, Hungary, Ireland, Italy, Latvia,	Lowest of Germany, Italy, Spain & UK	Free pricing market
Lithuania, Netherlands, Norway, Portugal,	Annual review (first 5 years) ????	16% national rebate
Spain, Sweden & UK	, , ,	HTA within 12 months
Annual review		
Netherlands	Spain	UK
Average of Belgium, France, Germany & UK	Lowest of Belgium, France, Germany, Greece, Ireland, Italy, Netherlands,	Free pricing market
	Portugal and UK	Rate of return balancing
Reviewed every two years	Ü	HTA following launch for selected products UK government is moving to "Value based
The management of the state of	Annual review	pricing"

Would external price referencing alone be a robust method on which to base prices for new medicines?

- 79% launches provided 4 or less basket countries
 - 50% of all launches provided 0 2 basket countries
- Less than 10% of launches have 7 to 9 basket countries.
- Germany & UK are most common prices provided
- Austria & Denmark are next most common
- Due to European launch sequences Ireland is often the first non free pricing launch country
- Austria is the only one of the 4 new countries added in 2006 agreement to feature in more than 25% of pricing baskets @ market launch
- "Official" list prices do not always reflect real prices in other countries e.g. Germany applies an automatic 16% rebate to new medicines

IPHA 2006

- Price realignments required at two time points
- 1 September 2008 all products priced as per agreement and available as at 1 September 2007 (changes implemented 1/11/08)
- 1 September 2010 all products priced as per agreement and available as at 1 September 2009 (changes implemented 1/11/10)

5.3 Price Monitoring and Review

The price to wholesaler of any new medicine introduced to Ireland under the new Agreement shall be realigned to the currency-adjusted average price to wholesaler in the nominated EU member states in which the medicine is then available, two years and four years following the commencement of the new Agreement.

Financial Outcomes

- Realigned prices: net benefit of €5.44M in 2011 based on 2010 annual product volumes (€98M reimbursed sales).
- 88.7% of realignment forms provided 4 or more baskets
 - 58.5% of total provided 7 9 basket countries
- 6.86% provided 0 − 2 baskets
- Price to wholesaler (PTW) remained the same for 35 products
- PTW Decreased for 176 products
 - Price reduction ranged from 0.22 70.99%.
 - €6.022M annual savings.
 - One product accounted for €1.16M of this
- PTW increased for subset of products
 - Price increases ranged from 0.1 48.92%.
 - €577K annual costs

External price referencing

- At launch may be of limited value from funders viewpoint other than as pointer of where company wishes to price
- Post launch pricing reviews do reduce prices and also might allow a small country to remedy any errors made in initial decisions??
- Limitations: What does each external price mean and are they real prices?
- If you don't rely on external price referencing alone what process can you use to price new medicines?
- Across Europe a move to increasing economic analysis as an input into decision making and pricing negotiations

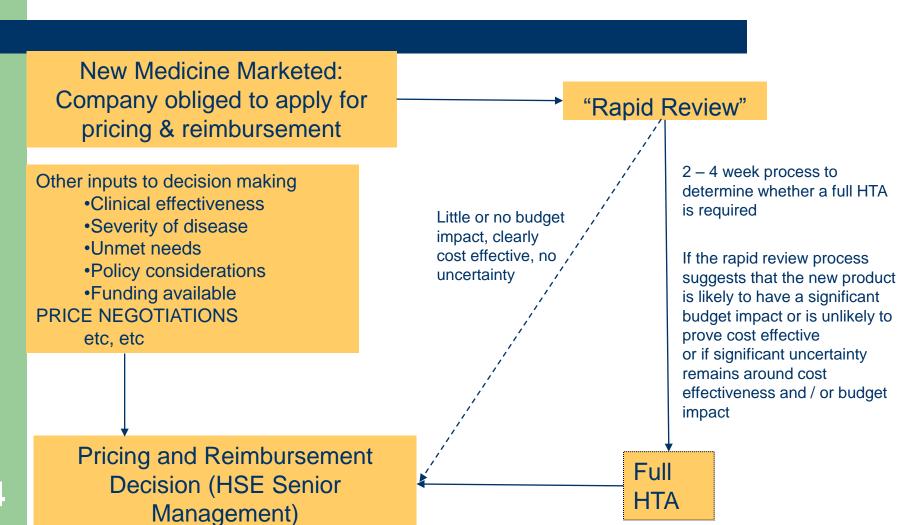
Decisions around new medicines have implications for other services



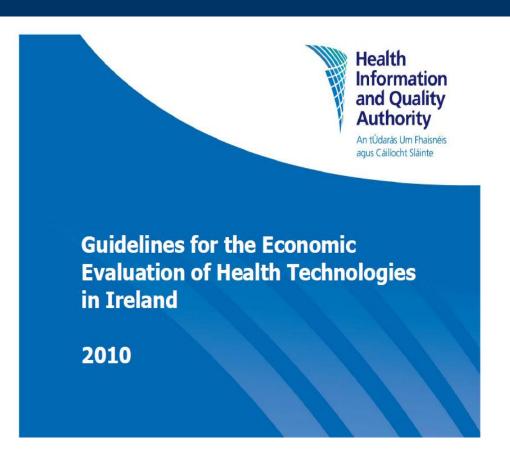




Health Technology Assessment



Health Technology Assessment (HTA) guidelines



5th October 2011

National Cancer Control Programme (NCCP) approves introduction of new diagnostic cancer test

(Oncotype DX) to be made available in all designated

Cancer Centres

NCCP Technology Review Committee

- Instituted March 2011
- The Committee is constituted of clinicians and additional representatives with expertise in epidemiology, statistics, pharmacy and pharmacoeconomics.
- Recommendations from the Committee are received by the National Director of the NCCP and subsequently brought forward to the HSE Senior Management Team.

Demand Side Measures



"First we're going to run some tests to help pay off the machine."

- Options available to maximise the potential of a limited budget
 - Reduce unit prices
 - Choose items with lower unit costs unless benefits outweigh cost differentials
 - Reduce volume by eliminating inefficient practises or choices
- Every choice has a consequence unless you have unlimited funds available

Choices

- Ireland 2008:
 - 11% 18% of prescription items dispensed generically
- England 2008:
 - 83% of prescription items prescribed generically
- Canada 2009:
 - 56% 61% of all prescriptions were generic

Reference Pricing

- Policy decision taken in 2010 to introduce a reference price system for some prescribed drugs
- Re-affirmed by current government
- Currently each product supplied has its own individual price
- Under reference price systems, groups of interchangeable medicines are determined
- Clinical exceptions are described / set down
- Reference pricing: same reimbursement price is set for a group of interchangeable (substitutable) products.
- Some suppliers may decide to price above the reference price
- Legislation awaited 'Programme for Government'

Choices

2009 data (Health Atlas)

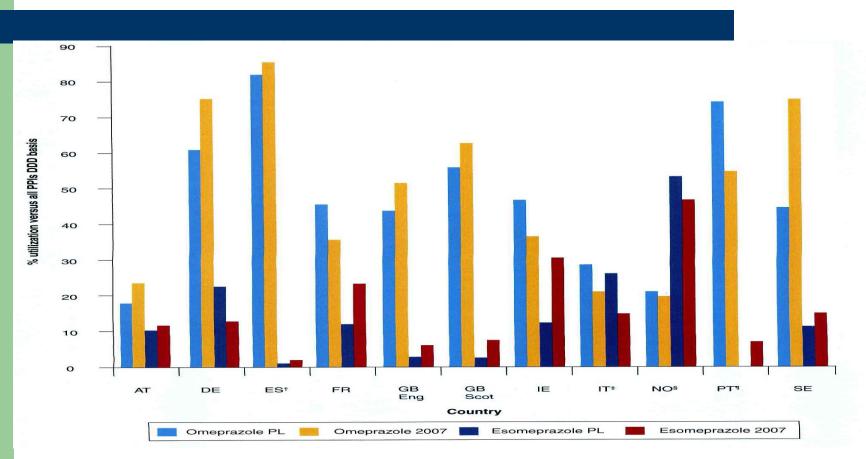
Wales

 71% of statins prescribed were for lower cost agents (Pravastatin / Simvastatin)

Ireland

- 23% of prescriptions were for lower cost agents
- In excess of 200,000 patients were receiving Atorvastatin.
- In 2009, 150,000 patients: Atorvastatin doses of 20mg or less
- If 70% had been lower cost agents at least €30M might have been available to invest in other services / other medicines

Choices



Expert Review Pharm Outcomes 10(6), 707-722 (2010)

Medicines Management

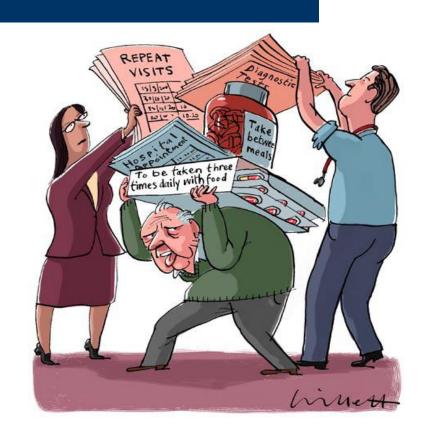
Typical approaches:

- Education guidelines, detailing, campaigns
- Engineering targets, indicators, formularies
- Economics incentives for quality indicators
- Enforcement restrictions or permissions

Adherence / Concordance / Compliance

- The untapped efficiency......
 - Reduce waste
 - Improve outcomes
 - Minimise ADRs
 - Minimise drug interactions





TORCH: (ClinicalTrials.gov number, NCT00268216.)

- 6112 patients, 42 countries, 444 centres
- Overall 875 (14.3%) of patients died within the 3 years
- All-cause mortality rates
 - 12.6% Combo group
 - 13.5% LABA alone
 - 16% ICS alone
 - 15.2% Placebo
- Reduced exacerbations, improved health status and spirometric values

- Adherence to inhaled therapy, mortality and hospital admission in COPD
- Post hoc review of TORCH data
- Good aherence > 80% use of study medication
- Poor adherence < 80%
- For every 7 patients with good adherence 1 extra patient was alive @ 3 years versus those with poor adherence

Vestbo et al Thorax 2009;64:939-943

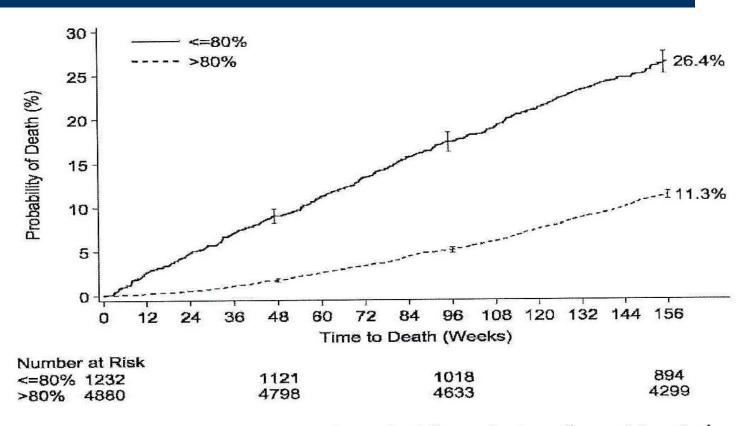


Figure 1 Kaplan-Meier plot of survival in patients adherent to study treatment and patients not adherent.

- Challenging funding background
- No additional funding expected
- Capacity to fund new medicines will be dependent on "efficiencies"
- Prescribing choices will and do impact on the availability of funds for investment in other services
- Influencing Patient choice and behaviour is complex

Thank You