Structural Barriers to Rational Therapy in Australia

“ The Silo Effect”

Richard Fox

The Silos

PBAC/PBS

MSAC

NHMRC

Medicare

The Future

- Demand for health services, particularly pharmaceuticals, will continue to increase and appears “insatiable”
- Aging population - more demand, less capacity to pay

Translational Research

1. Bench to bedside

2. Application of “evidence” based clinical information.

Impact of New Technologies

1. Molecular Pathology : genetic markers as specific targets
2. Biotechnology : new drugs - small molecules
   - McAb
3. Imaging Technology : CT
   PET
   MRI

PBS Expenditure

1991	$1.2 billion
2001	$4.1 billion
2003	$4.5 billion

Growth rate fluctuates at 6-20% per year

Just announced Anti-Cancer Drug Expenditure

Agent	PBS cost per year (millions)
Sunitinib (renal)	$34
Avastin (colorectal)	$78
Herceptin (breast)	$42

Metastatic Colo-Rectal Cancer "Erbitux" (Cetuximab)

- Of value only in patients whose tumours have an intact K-Ras

- Australian G I Study Group, N.E.J.M. 2008

Herceptin (Trastuzumab)

- Recombinant humanised monoclonal antibody
- Selectivity binds with high affinity to extracellular domain of HER2 (Human Epidermal Growth Factor Receptor)
- HER2 : overexpression/gene amplification is an adverse prognostic factor in breast cancer
- Activation of antibody-dependent cellular cytotoxicity by McAb destroys tumour cells.

Adjuvant Herceptin
HER2 Positive Early Breast Cancer

- Initial trials of one year of Herceptin
- Reduce risk of recurrence by ≈50%
- Reduce risk of death by ≈33%
- Median follow up 2 years

Adjuvant Herceptin
HER 2 Positive Early Breast Cancer

- One year course PBS approved
- Cancer biopsy must be HER 2 positive
  - IHC level 3 (on 0-3 scale)

  or - positive result with ISH
- Cost approx. $50,000/year.

Adjuvant Herceptin

Secondary Trials: European Government Support

1. France/Europe : 6/12 vs 12/12 Herceptin
2. Finland : 3/12 vs 12/12 Herceptin

Australian GI Study Group and the international "SCOT" Study

- Adjuvant chemotherapy in colorectal cancer
- Folfox/Oxaliplatin
- 12 weeks v/s 24 weeks (the standard)

“Tailor X” Trial

- Stage II breast cancer.
- Kit to determine expression of 21 molecular targets.
- Separates patients into “poor”& “good” prognosis.
- Allows randomisation to +/- adjuvant chemo.
- Elimination of chemo in 50% outweighs trial cost.

A Quandary : Requirement for funding of "Hybrid Technologies"

- Treatment modality linked with
  - molecular pathology or
  - specific imaging criteria
- But PBAC
  MSAC unlinked silos

PBAC / PBS/MSAC

- Inflexible
- Regimes / Indications submitted by Pharma Sponsor become outdated, inappropriate and restrictive.

rm1

Inability to Commission Research

- PBAC
  MSAC
  Medicare, NHMRC

- "Post marketing surveillance" to optimise
  - drug dose
  - treatment duration
- Use of Australian clinical research groups linked internationally
- Europe uses Government funds, independent of "Big Pharma".

Slide 17

rm1 fox, 4/08/2009

Necessity

- Greater involvement of all stakeholders in the debate on future sustainability of the PBS.

Can PBS Change?

- Long process, need for “Vision and Pragmatism” (Obama)

"Emerging Technology Assessment Group' (ETAG)

PBAC

MSAC

Medicare

NHMRC

1. Recognise emerging issues re funding
2. Commission appropriate trials, collaboration with European groups
3. Trials are cost neutral
4. Overcome inability to fund such trials via "Health Dollar Offset Trading Scheme" between PBAC, MSAC, Medicare, etc. as form of post-marketing surveillance