(How) can Australia's experience inform the architecture of a national drug plan for Canada?

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A Prescription for Equity

A NATIONAL PUBLIC DRUG PLAN FOR ALL

10-11th April, 2017

Canadian Health Coalition / Coalition canadienne de la santé

Australia's health care system

A federation of 6 states and 2 territories

- population ~24 million

National single payer model **'Medicare'**

- universal coverage for all Australians since 1980s
- federal income tax and VAT funded
- key principle of **universal, equitable access** regardless of ability to pay

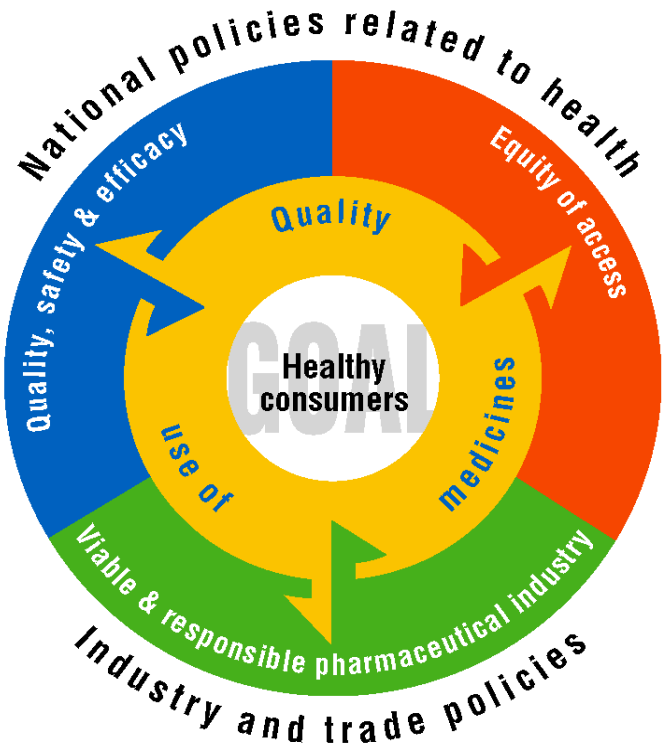
Three components:

- Medicare Benefits Scheme (MBS) for primary and ambulatory care, diagnostics/pathology, some allied health
- **Pharmaceutical Benefits Scheme** (PBS) subsidized access to a comprehensive range of outpatient prescription medicines
- Transfers to the states and territories cover funding for public hospitals

National Medicines Policy

The NMP has four central objectives

- Medicines meeting appropriate standards of quality, safety and efficacy
- Timely access to the medicines that Australians need, at a cost individuals and the community can afford
- **Quality use** of medicines
- Maintenance of a responsible and viable medicines industry



Milestones in pharmaceutical coverage

Pharmaceutical benefits for war veterans 1919

1946 Constitutional amendment needed to allow the Commonwealth Government to introduce a national drug subsidy programme

- first step toward universal coverage
- initial subsidy of 138 'life-saving and disease-modifying' drugs

National Health Act 1953 established the Pharmaceutical Benefits Advisory Committee (PBAC) – independent expert committee

- formulary addition initially based on clinical need
- legislated requirement to consider comparative effectiveness and **value for money** *(4th hurdle process)* since early 90s

Pharmaceutical Benefits Scheme today

PBS established **nearly 70**

- **universal access** to cost **outpatient** Rx medicines
- operates a single **national formulary**

Approx. 80% of all prescriptions dispensed are PBS subsidized

- demand driven program with no fixed appropriation

No direct price regulation

- requirement to demonstrate value for money indirectly moderates prices
- **no price regulation** outside the PBS

Key 'Architectural' Elements of the PBS

- National medicines policy context – equity, affordability, need
- Universal, comprehensive coverage for outpatient Rx meds
- Coverage of registered indications only, with restrictions where necessary
- Paradigm of *purchasing outcomes,* not drugs
- Patient contributions fixed – no coinsurance
- Value based pricing for patented meds, competition for off patent meds
- Subsidy on basis of comparative effectiveness and cost, relative to alternatives
- A drug substantially more costly than alternatives cannot be listed unless it provides a significant increase in efficacy or reduction in toxicity, or both
- Minister cannot list without positive recommendation from the expert committee (PBAC)

PBS Formulary Listing Process

PBAC reviews submissions proposing new medicines for the PBS formulary

- passive process reliant on applicant
- a medicine may only be added to the formulary if evidence it is effective, safe and cost effective compared with the therapy most likely to be replaced in practice
- comparative cost-effectiveness essential, but not sole criterion and no fixed cost-effectiveness threshold

PBAC also weighs a range of relevant factors, including

- clinical need;
- uncertainty;
- budget impact;
- scope for 'leakage', and whether an effective restriction is possible;
- affordability in the absence of a subsidy

No appeal process but applicant may seek independent review of issues in dispute

- judicial review available for matters of process
- resubmission if new data

Restrictions

Used to target drugs to indications, patient groups or clinical settings, a medicine may be listed as :

- an *unrestricted* benefit,
- a *restricted* benefit (should only be prescribed for specific indications)
- an *authority required* benefit (with prior authorization)

Restrictions may be applied in order to:

- limit PBS usage to approved indications
- allow controlled introduction of a drug in a new therapeutic class
- limit PBS usage to indications, conditions or protocols appropriate for clinical, cost-effectiveness, or other reasons
- alleviate concerns about possible misuse, overuse or abuse

For selected medicines initiation and continuation rules and stepped therapy algorithms may also be applied

Transparency and contestability

- PBAC meetings held *in camera*
- Sponsors may request a hearing before PBAC
- Sponsors may seek an independent review of a negative outcome – or may resubmit
- Consumers and clinicians encouraged to comment on agenda prior to meetings
- Public Summary Documents are made available on the PBS website

PBAC has made progress on transparency but more needs to be done

No individual review or appeal – decisions made on population basis.

Pricing and Risk Sharing

No direct price regulation, but **effective monopsony** heavily influences prices

Underlying principle of '**purchasing outcomes – not drugs**'

- reference pricing for generic medicines and defined therapeutic groups
- 'price disclosure' <=> competition in off patent market
- price negotiation after listing recommendation
- high cost drugs or risk of 'leakage'
  - initiation and continuation rules
  - risk sharing arrangements: price-volume agreements, hard expenditure caps with rebates, "Managed Entry" agreements

Patient co-payments

First introduced in 1960

Currently 2 levels of **fixed co-payments** irrespective of drug cost + **safety net thresholds**

- General: ≤ ~CAD 40 (CAD 1,530, thereafter at concessional rate)
- Concessional: ≤ ~CAD 7 (~ CAD 390, thereafter *gratis*)

Annual adjustment in line with Consumer Price Index (CPI).

Issue of affordability for working families (eg no concessions for children)

- growing impact on adherence
- both sides of politics seem firmly wedded to concept of moral hazard

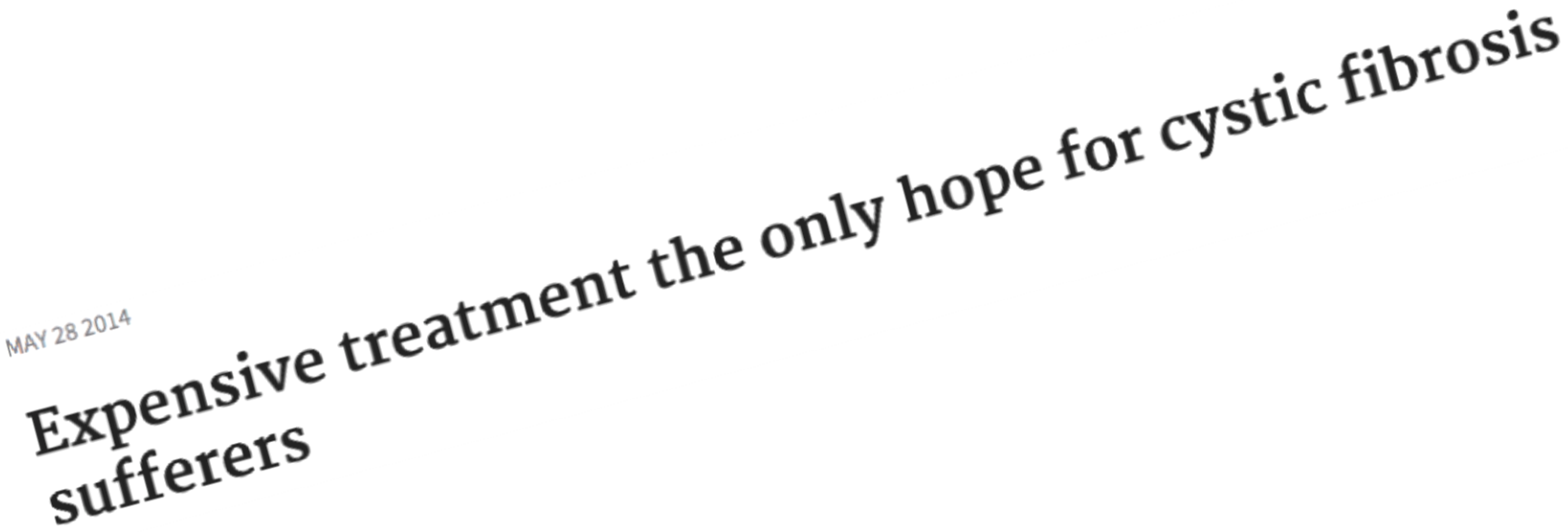
A Debate on High Cost Drugs and Social Values is Overdue

Unlike the UK, Australia has not yet had an extensive public or media debate on expensive lifesaving drugs or end-of-life therapies.

- to date there has been no formal debate on social value judgments and their role in PBAC decision-making.

From time to time, awareness of PBAC's consideration of a particular therapy will generate controversy,

- decisions to reject certain drugs attract media, industry and public criticism
- but *price and effectiveness are rarely questioned*
- almost no discussion of the opportunity costs of expensive therapies.



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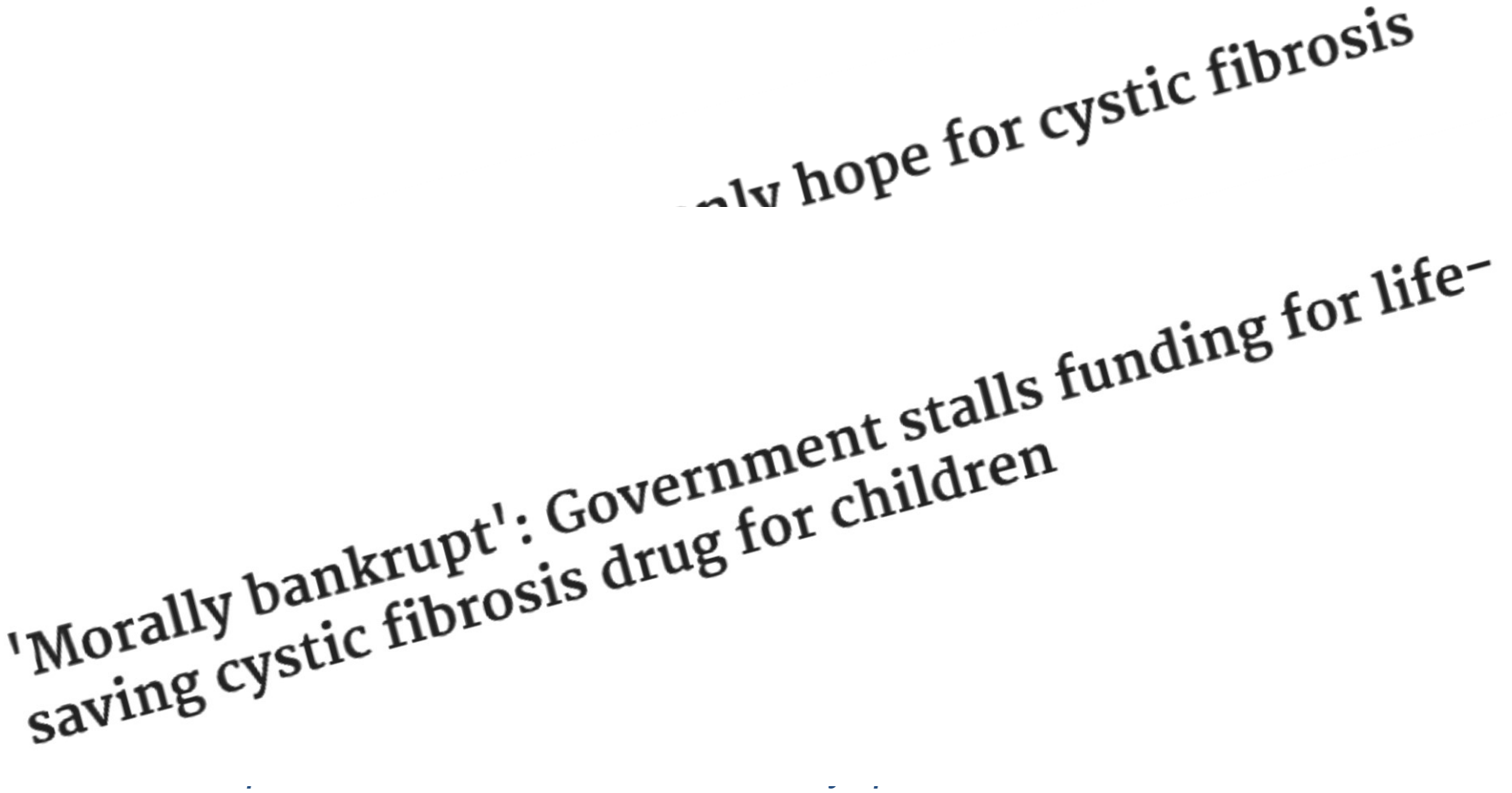

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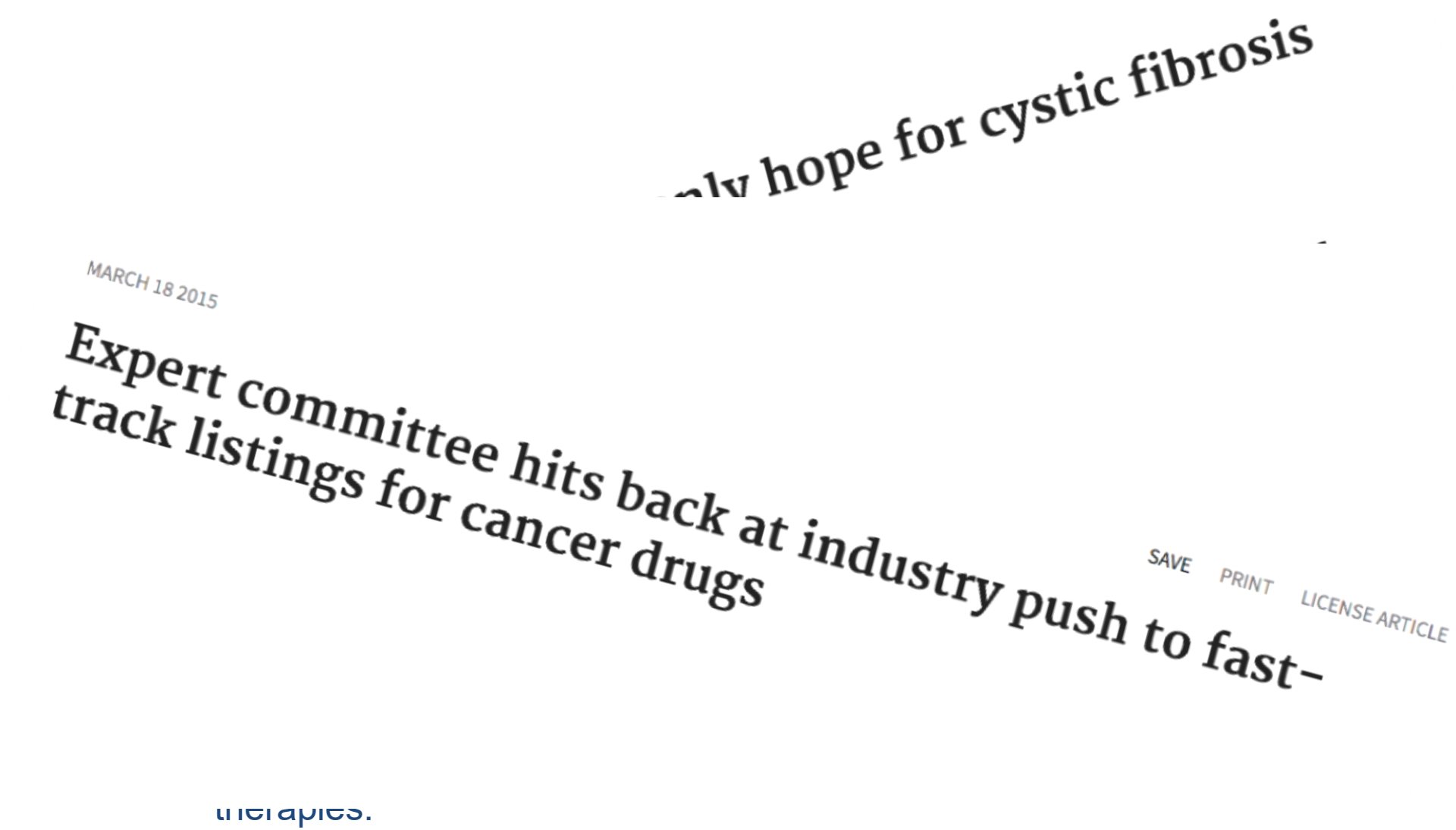
hope for cystic fibrosis
MARCH 18 2015
Expert committee hits back at industry push to fast–track listings for cancer drugs
SAVE
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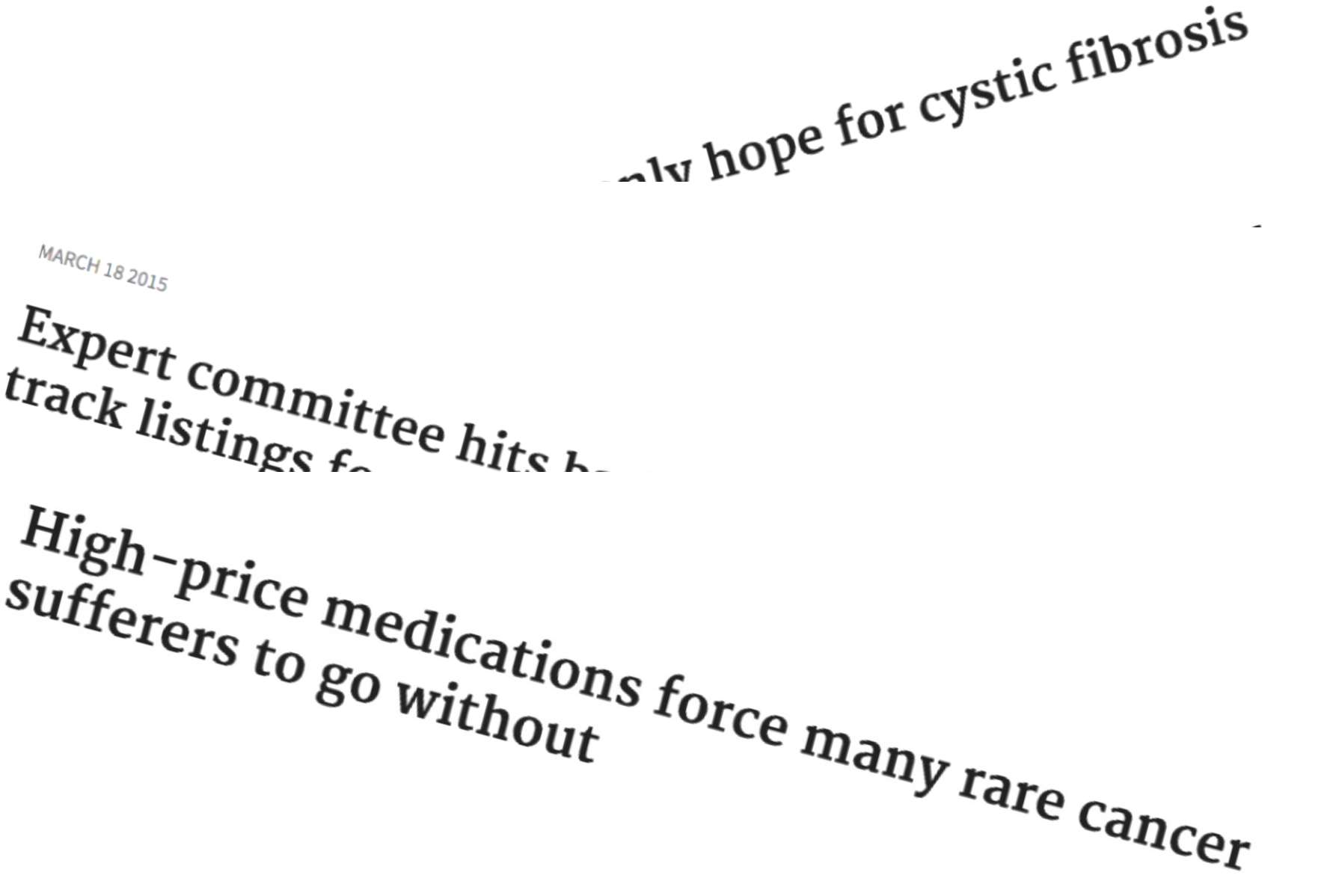
therapies.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Canada vs Australia: prices and expenditure

Spending comparison

Health and pharmaceutical spending 2014				
	GDP (CAD) per capita, 2014	Total health spending, CAD per capita, 2014	Total pharmaceutical spending, CAD per capita, 2014 or closest year	Total pharmaceutical spending, relative to Canada
Canada	$55,510	$5,543	$952	0
Australia	$57,552	$5,187	$772	-19%

Price comparisons

Drug	Indication	Dose/Quantity	Australian PBS Price (USD)	Canadian Price (USD)	Australian price relative to Canadian price
Xtandi (enzalutamide)	Prostate cancer	40mg x 120	3,539	4,990	-29%
Sprycel (dasatinib)	Chronic myeloid leukemia	50mg x 60	3,630	4,519	-20%
Gllenya (fingolimod)	Multiple sclerosis	500mcg x 84	5,292	11,652	-55%
Harvoni (lepidasvir/sofosbuvir)	Hepatitis C	90mg/400mg x 28	16,933	28,187	-40%

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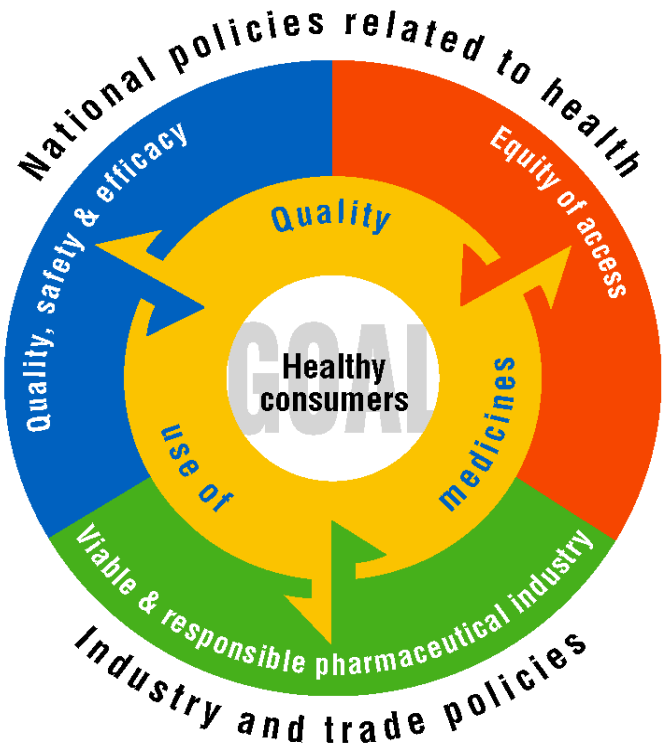

Quality Use of Medicines - the NPS

NPS was established in1998, to enable

'better decisions about medicines'

- Assists HCPs keep up to date with latest evidence
- Provides consumers with tools and knowledge to make better decisions.
- Internationally recognized for its work in QUM
  - health professional education
  - www.nps.org.au, partner sites and social media
  - national awareness campaigns and media
  - peer education workshops
  - publications including *Australian Prescriber* and *NPS RADAR*
  - medical under- and post graduate education, uniform prescribing curriculum
  - e-health applications and tools
  - policy and standards development

NPS RADAR
Rational Assessment of Drugs and Research

Key challenges for policymakers

- Demand side - QUM and preventive programs
- Supply side - maintain cost effectiveness as key criterion for listing
- Stakeholders must share responsibility for maintenance of the system into the future (greater transparency is essential for this)
- Improving public engagement and better reflecting societal values
- Incremental improvements in treatments (but costing $$$)
- Finding the balance between efficiency and equity, equity and sustainability…
- … and between health and industry portfolio objectives

Final thoughts

- Despite criticism, the PBS is **highly valued** and **strongly defended** by public, professions, and the states and territories
- Federal ownership of the program **reduces burden** on states and territories, **ensures equity,** reduces duplication of effort
- Federal **monopsony power** a key factor in moderating prices, ensuring **value for money**, supporting **sustainability**

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