

*Centre for International and Public Law and Faculty of Law Australian National University and Australian and New Zealand Society for International Law*

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***Global Public Health: Multilateral and Bilateral Trade Efforts Regarding Pharmaceutical Intellectual Property***

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# *Content*

- ❖ Outlines interaction between multilateral and bilateral agreements to facilitate hegemonic interests to “eliminate” pharmaceutical price controls, whatever their social value

# *Pharmaceutical Innovation*

- ❖ To sustain a 15% annual growth rate a pharmaceutical company needs to discover 8-9 new molecular entities (NMEs) each year (10% growth rate needs 5-6 NMEs and 5% growth rate 2-3 NMEs)
- ❖ Current industry average is 0.5 NME's per year
- ❖ Evergreening of brand name blockbuster patents provides an alternative (multiple techniques)

# *Pharmaceutical Innovation*

- ❖ Effective first-line treatment for 96% of all medical problems requires access to about 300 existing medicines.
- ❖ 18% of the R&D budgets of PhRMA's members goes to discovering "breakthrough" drugs. Most is spent on making minor variations to existing, profitable "developed-nation-disease" medicines. Pharmaceutical company profits, after R&D costs have been removed, are conservatively estimated to be three to four times the profits of other US companies.
- ❖ R Laing B Waning, A Gray et al, 25 Years of WHO Essential Medicines List: Progress and Challenges (2003) 361 Lancet 1723-1729, Families USA, Out of Bounds: Rising Prescription Drug Prices for Seniors. Washington DC 2003. National Institute of Health Care Management, Prescription Drugs and Intellectual Property Protection. Washington DC (2000).

# *TRIPS Agreement*

- ❖ *Convention on Trade Related Intellectual Property Rights*
- ❖ An initiative of Industry CEOs, including US PhRMA
- ❖ Uses trade sanctions to enforce higher intellectual property standards
- ❖ Exceptions created by *Doha declaration on TRIPS and Public Health* circumvented by US bilateral trade deals using Article 4 MFN (but ? TRIPS-Minus)
- ❖ NVNB claims permitted by Article 64

# *AUSFTA and Pharmaceutical Pricing*

- ❖ The Australian-United States Free Trade Agreement (“AUSFTA”) entered into force 1 January 2004
- ❖ First such bilateral US Trade Deal to include specific provisions on a developed nation’s pharmaceutical reference pricing system
- ❖ Such systems are a significant part of global public health regulation

# *US Trade Negotiators' Agenda to Seek the "Elimination" of Reference Pricing Systems*

- ❖ *Medicare Prescription Drug Improvement and Modernization Act 2003 21 U.S.C conference agreement*
- ❖ *Trade Act 2002 (US), 107-210 §2102 (b) (8) (D).*

# *US Study of Reference Pricing Systems in OECD Countries*

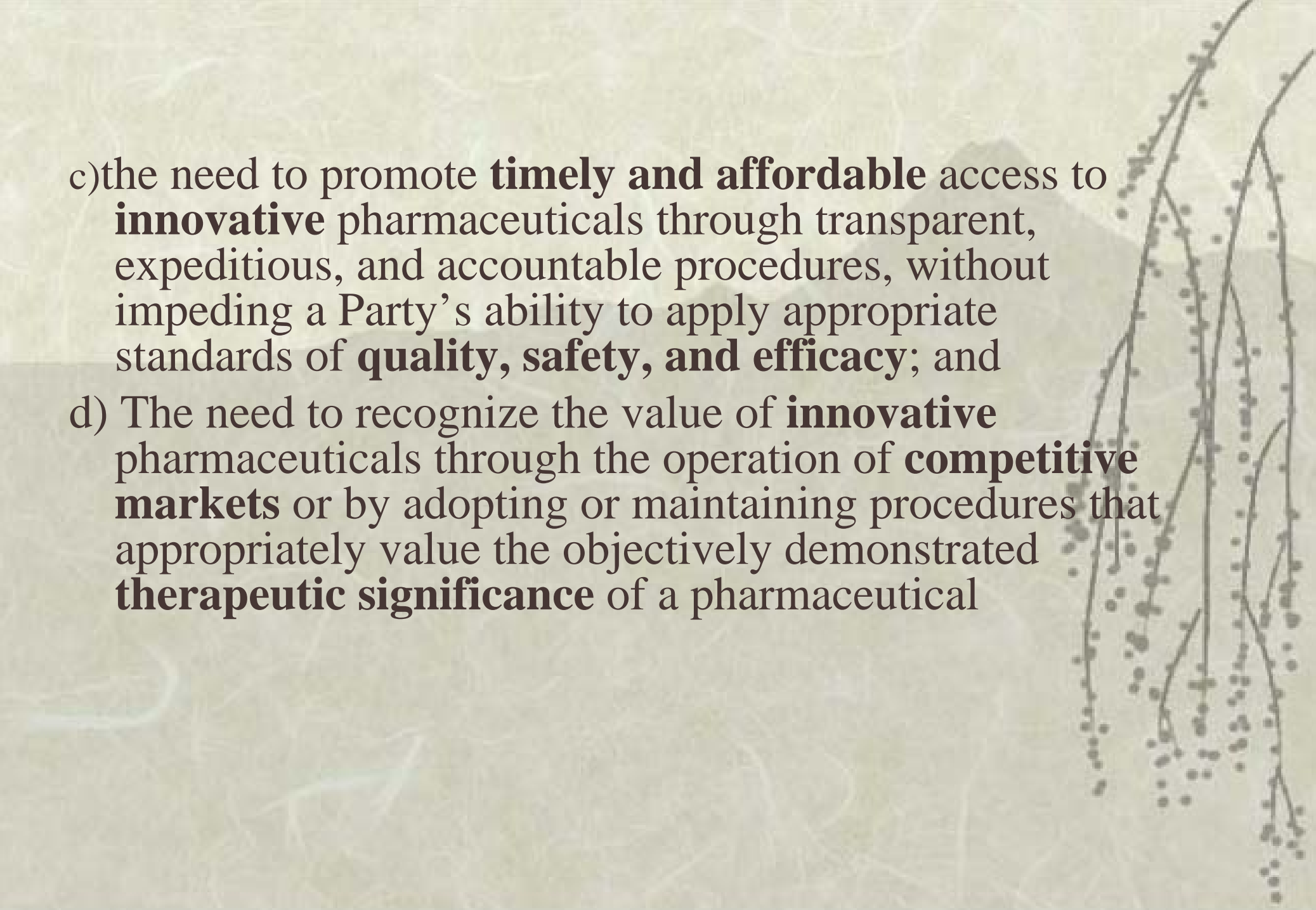
- ❖ US Dept Commerce
- ❖ Commissioned by *Medicare Prescription Drug Improvement and Modernisation Act (2003)*
- ❖ Includes France, Germany, UK, Greece, Switzerland
- ❖ Plan to dismantle reference pricing systems in these countries and make their medicines prices move to higher US benchmark
- ❖ Endorsed by *Medicines Australia* in its submission to Productivity Commission of Medical Technologies

# AUSFTA, Annex 2C on Pharmaceuticals.

## Interpretive Principles

The Parties are committed to facilitating high quality health care and continued improvements in public health for their nationals. In pursuing these objectives, the Parties are committed to the following principles:

- a) the important role played by **innovative** pharmaceutical products in delivering high quality health care
- b) the importance of **research and development** in the **pharmaceutical industry** and of appropriate government support, including through **intellectual property protection** and other policies

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- c) the need to promote **timely and affordable** access to **innovative** pharmaceuticals through transparent, expeditious, and accountable procedures, without impeding a Party's ability to apply appropriate standards of **quality, safety, and efficacy**; and
- d) The need to recognize the value of **innovative** pharmaceuticals through the operation of **competitive markets** or by adopting or maintaining procedures that appropriately value the objectively demonstrated **therapeutic significance** of a pharmaceutical

## *Other Key AUSFTA PBS Provisions*

- ❖ Article 17.10.4: “Marketing approval” by TGA of Generic Drug must be “prevented” when any type of patent is “claimed” by a brand-name manufacturer (evergreening)
- ❖ Article 21.2(c): Non Violation Nullification of Benefits (applies to Annex 2C and Ch 17)

# *Democratic Legitimacy of PBS*

- ❖ 1948 Federal Legislation for Formulary of Free Medicines ruled Unconstitutional
- ❖ Successful referendum adding s51xxiiiA
- ❖ 1949 Legislation creating Pharmaceutical Benefits Scheme (“PBS”) ruled constitutional
- ❖ Legislation amended and enhanced by successive governments

# *PBS is Based on Medicine Cost Effectiveness and Generics*

- ❖ Section 101 (3A-3C) of *National Health Act 1958* (Cth) requires PBAC to base recommendation on: “the effectiveness and **cost** of therapy involving the use of the drug, preparation or class, including by **comparing the effectiveness and cost of that therapy with that of alternative therapies**, whether or not involving the use of other drugs or preparations...[if] **substantially more costly..shall not recommend...**
- ❖ unless...provides a significant improvement in efficacy or reduction of toxicity over the alternative therapy or therapies

# *Reward of Pharmaceutical Innovation and Pressure on the PBS*

- ❖ Expect increased submissions to PBAC by US pharmaceutical companies claiming Annex 2C justifies “breaking” the reference class, or a “price premium” for innovation
- ❖ They will probably use refusal of such claims to provide the “substantial justification” required by article 26 of the WTO DSU for a NVNB claim under article 21.2(c)

## *Australia and AUSFTA NVNB Claim*

- ❖ Australia can also mount a NVNB claim under article 21.2 (c) on the basis that continuance of cost-effectiveness pricing was a “benefit” we reasonably expected
- ❖ Need to establish that these PBS claims are a “measure” nullifying or impairing our “benefit” (Inchon Airport case)
- ❖ Benefits of either side are not clear under Annex 2C

# *Parliamentary Sovereignty v Corporate Sovereignty*

- ❖ THE ANTI\_EVERGREENING AMENDMENTS
- ❖ New 26B requires notice by generic to brand name mfg and certificate that brand name patents not infringed (implementing article 17.10.4 AUSFTA)
- ❖ New 26C of TGA: brand name manufacturer must lodge certificate if contesting generic entry
- ❖ New 26D TGA: brand name mfg must give notice of injunction against generic to Cth Att-Gen who can join and claim damages for losses to the PBS from delayed generic entry arising from the injunction.

# *Conclusion*

- ❖ Trade agreements providing enforcement arm for corporate sovereignty over pharmaceutical cost-effectiveness pricing
- ❖ No democratic mandate for these changes
- ❖ Popular sovereignty marginalized through corporate capture of State in key policy areas
- ❖ Normative discourse of public health law and international human rights marginalized