The TPP and Biologic Medicines

DR DEBORAH GLEESON

SCHOOL OF PSYCHOLOGY AND PUBLIC HEALTH, LA TROBE UNIVERSITY

TRANS PACIFIC PARTNERSHIP: IMPACT ON THAILAND'S ECONOMY, SOCIETY, AND HEALTH SYSTEM

BANGKOK, 9 AUGUST 2016

TPP chapters with implications for access to medicines

- **Intellectual property chapter (Ch 18)**
- Investment chapter (Ch 9)
- Healthcare Transparency Annex (Annex 26-A: Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices)
- Technical Barriers to Trade (Ch 8), Annex 8-C (Pharmaceuticals)

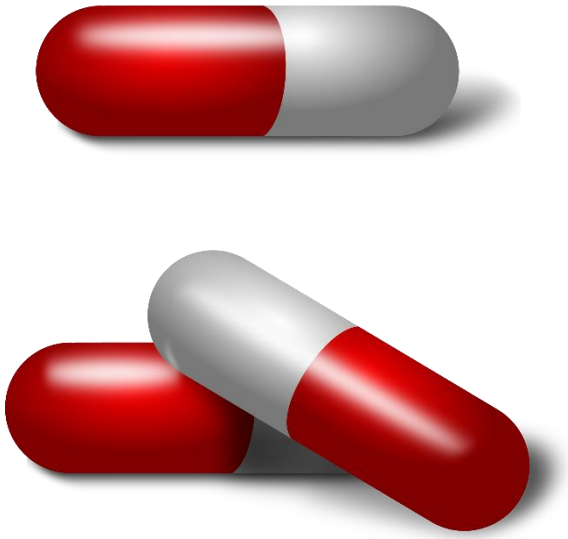


Image: Pixabay

Trips-plus provisions in the final TPP intellectual property chapter

- Mandatory secondary patents (combined with low inventiveness threshold)
- Patent term extensions
- Data protection for small molecule drugs
- **Market exclusivity for biologics**
- Patent linkage

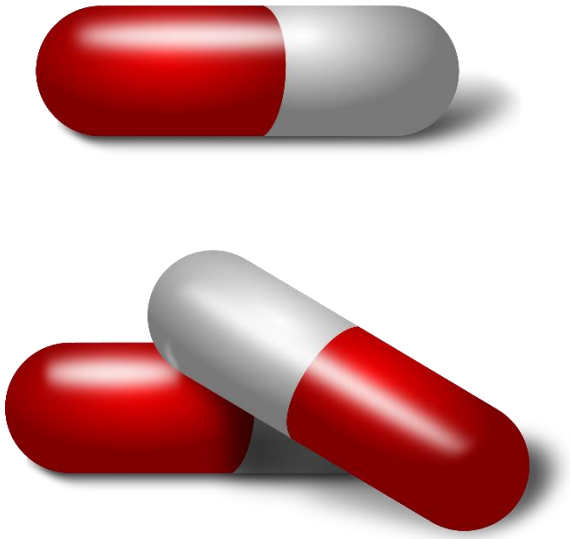


Image: Pixabay

Biologics and biosimilars

- Biologics
  - Produced through biotechnological processes using living organisms
  - Include vaccines, treatments for cancer and immune conditions
  - Emerging class of products, complex, expensive
  - Predicted to make up 19-20% of global pharmaceutical sales by 2017 ($US 221 bn)
  - 64 listed on Australia's Pharmaceutical Benefits Scheme (PBS) in 2013
- Biosimilars
  - Follow-on versions that can be produced at a lower cost

Recent PBS listings:

Keytruda
- Metastatic melanoma
- $156,130 per patient/year

Adcetris
- Lymphoma
- over $110,000 per patient/ year

Image: Pixabay

Data protection

- Monopoly protection different to a patent – guaranteed exclusivity
- Originator submits clinical trial data to regulator as evidence of safety and efficacy
- Generic/biosimilar manufacturers cannot rely on this data to register follow on versions for a period of time
- **Australia currently has 5 years of data protection for all medicines**
- **Some TPP countries do not currently provide data protection for biologics**
- Initial US demand for biologics in TPP: 12 years
- **Late stage US 'compromise': 8 years**

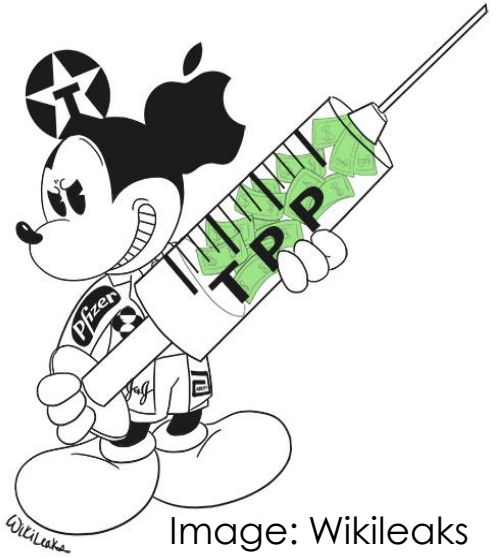


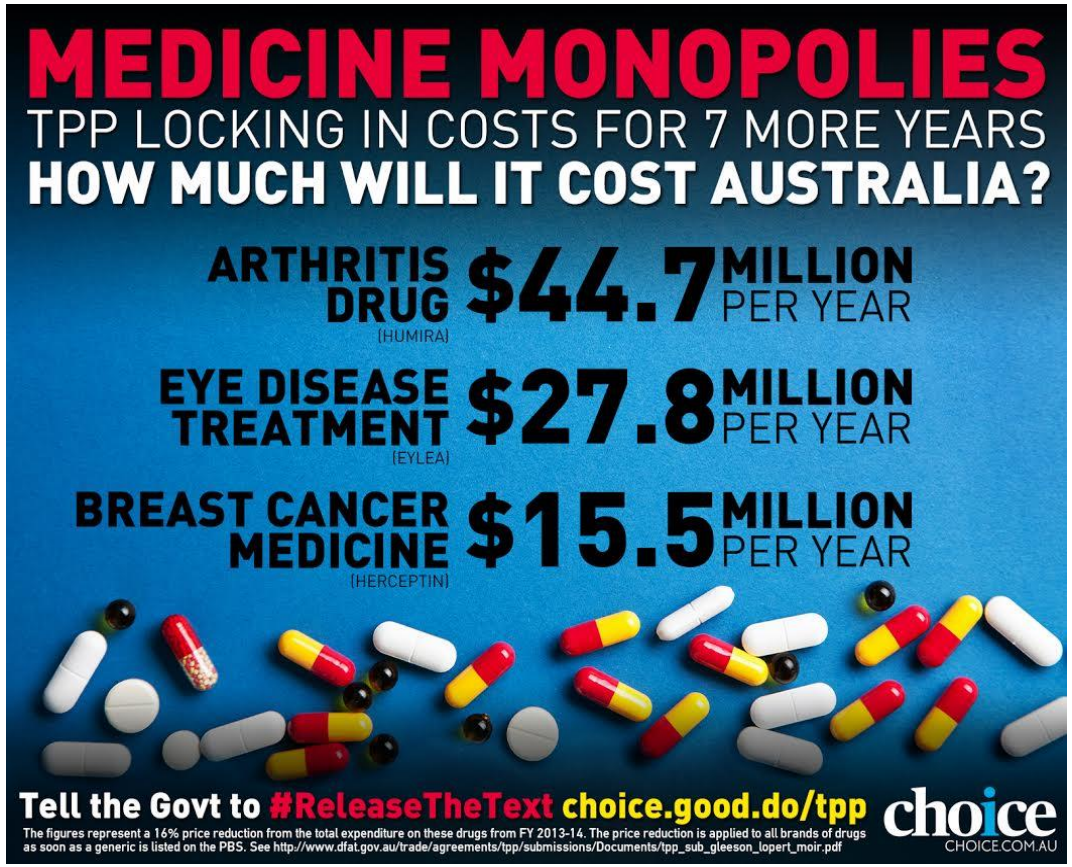
Image: Wikileaks

Medicare expenditure on top 10 biologics

Drug (Brand)	Drug (INN)	Expenditure 2013-14 $A
Humira	adalimumab	279,391,117
Enbrel	etanercept	159,276,422
Eylea	aflibercept	173,444,968
Lucentis	ranibizumab	175,348,775
Prolea, Xgeva	denosumab	61,676,426
Simponi	golimumab	57,829,452
Stelara	ustekinumab	40,944,165
Mabthera	rituximab	164,865,590
Avastin	bevacizumab	77,300,861
Herceptin	trastuzumab	96,979,810
TOTAL		1,287,057,586

TPP and cost of biologic monopolies in Australia

- 10 expensive biologics = almost $1.3 billion in taxpayer-funded subsidies (14% of PBS expenditure in 2013-14)
- Price will drop by 16% when a biosimilar (follow-on) is available
- $205.9 million would have been saved if biosimilars were available in 2013-14
- Keeping these drugs under monopoly costs hundreds of millions per year



Gleeson et al, 2014 – submission to DFAT

Final biologics provisions

- 18.52.1 Length of market exclusivity: 2 options
  - (a) At least 8 years' protection of clinical trial data OR
  - (b) at least 5 years' protection of clinical trial data along with "other measures" to "provide effective market protection" and "deliver a comparable outcome in the market"
- 18.52.2 Broad definition of biologics
  - …at a minimum, a product that is, or alternatively contains, a protein produced using biotechnology processes, for use in human beings for the prevention, treatment or cure of a disease or condition.
- 18.52.3 Review of length and scope of exclusivity after 10 years

Market exclusivity for biologics (Article 18.51)

- Developing countries
  - Brunei, Chile, Malaysia, Mexico, Peru and Vietnam need to provide data protection for biologics for the first time
- Transition periods:
  - Chile: No transition period
  - Brunei: 4 years
  - Malaysia, Mexico: 5 years
  - Peru: 10 years
  - Vietnam: 10 years plus possible extension to 3 extra years

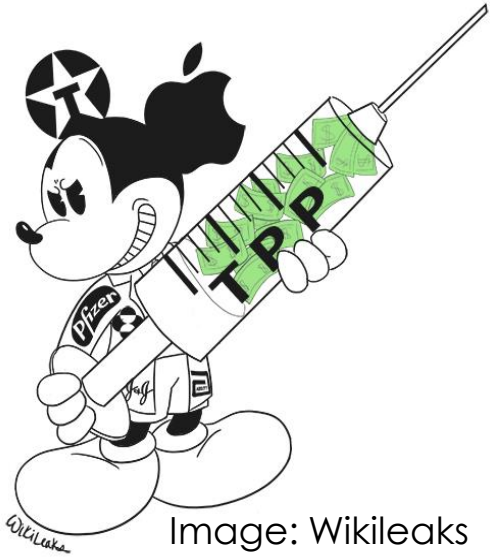


Image: Wikileaks

Market exclusivity for biologics (Article 18.51)

- Developed countries
  - Locked into existing arrangements
    - US: 12 years; Japan 8 years; Canada 8 years agreed under CETA
    - Australia, New Zealand, Singapore: 5 years
  - Legal language leaves room for US to pressure for equivalent to 8 years
  - Length of data protection period a major outstanding issue for Republicans in Congress; USTR claims biologics provisions provide 8 years' exclusivity

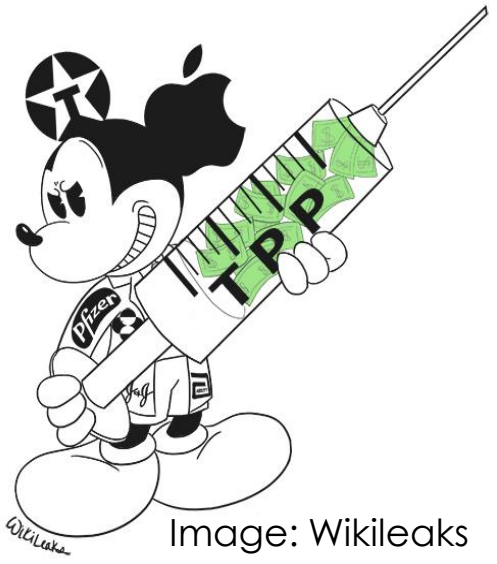


Image: Wikileaks

Risks: biologics provisions

- If Article 18.51.1(b) is interpreted to provide for the equivalent of eight years of market exclusivity:
  - For Australia to ***guarantee*** that a biologic would receive eight years of market exclusivity would require the introduction of new obstacles in the regulatory processes.
  - Potential for disputes if a biosimilar reaches the market in less than eight years; difficult to predict how Article 18.51.1 would be interpreted by a tribunal.
  - The biologics provisions may have a chilling effect on the introduction of new measures to facilitate the faster availability of biosimilars.

Conclusion

- Biologics: very expensive and taking up an increasing share of pharmaceutical expenditure
- Large cost burden associated with maintaining/lengthening monopolies
- TPP: first trade agreement to require market exclusivity for biologics
- 6 developing countries will need to provide market exclusivity for biologics for the first time
- Short inflexible transition periods for developing countries will delay costs for only a short time
- Even in wealthy countries, TPP biologics provisions will lock in existing settings and risk delaying availability of biosimilars

References

- Gleeson DH, Moir H and Lopert R. (2015) Costs to Australian taxpayers of pharmaceutical monopolies and proposals to extend them in the Trans-Pacific Partnership Agreement. *Medical Journal of Australia*, 202(6). https://www.mja.com.au/journal/2015/202/6/costs-australian-taxpayers-pharmaceutical-monopolies-and-proposals-extend-them
- Gleeson D, Lopert R, Moir H (2014) Proposals for extending data protection for biologics in the TPPA: Potential consequences for Australia. Submission to the Department of Foreign Affairs and Trade, 13 December 2014. http://dfat.gov.au/trade/agreements/tpp/negotiations/Documents/tpp_sub_gleeson_lopert_moir.pdf
- Hirono K, Haigh F, Gleeson D, Harris P, Thow AM, Friel S. (2016) Is health impact assessment useful in the context of trade negotiations? A case study of the Trans Pacific Partnership Agreement. *BMJ Open* 2016;6:e010339 doi:10.1136/bmjopen-2015-010339
- Inside U.S. Trade (2016) Froman: Biologics Is The Major Outstanding TPP Issue For Congress. 17 June 2016.
- IMS (2013) The Global Use of Medicines: Outlook Through 2017.
- Lexchin J and Gleeson D. (In Press) The Trans Pacific Partnership Agreement and pharmaceutical regulation in Canada and Australia. *International Journal of Health Services.*
- Ruckert A, Schramm A, Labonte R, Friel S, Gleeson D, Thow AM (2016) Policy Coherence, Health, and the Sustainable Development Goals: A Health-Impact Assessment of the Trans-Pacific Partnership. *Critical Public Health*, published online 27 April 2016.