We are not aware of any analyses of the financial impact of data protection on the Australian health system, but studies in other countries have shown that its introduction leads to increased costs. Oxfam International found that data protection introduced in Jordan in 2001, together with other TRIPS Plus measures, delayed generic entry for 79% of medicines launched between 2002 and 2006. A later, more comprehensive study found that between 1999 and 2004 there was a 17% increase in total medicines expenditure in Jordan, equating to additional costs of US$18 million in 2004. The study concluded that data protection had the most significant effect on this price increase.

In addition to its effects on medicines expenditure, data protection also presents a potential barrier to compulsory licensing — a TRIPS-compliant strategy that countries may use to bypass patents where this is necessary for public health purposes.

Proposals for the TPPA include 5 years of data protection for new products, an additional 3 years for data produced to support new uses of existing products, and a longer period of data protection for biologics (possibly up to 12 years). Biologics are produced through biotechnology processes involving living organisms; these include many new cancer, anti-rheumatic and multiple sclerosis medicines.

In the 2014 TPPA draft, data protection is limited to undisclosed data and data required by regulatory agencies, representing a narrowing of the scope in comparison with earlier drafts. However, extending data protection to new uses of existing products and allowing longer periods of protection for biologics is likely to lead to significant delays in the market entry of cheaper generics and biosimilars in Australia. Additional periods of 3 years of data protection for new indications were previously rejected by Australia in the AUSFTA negotiations.

The PPR found that “data protection appears to have little impact on the levels of pharmaceutical investment in a country”. It concluded that there was no evidence to indicate that current data protection provided insufficient incentives to innovate and bring biologic products to market, and recommended against extending data protection for biologics. In the US, the Federal Trade Commission also concluded that lengthy data protection for biologics was not warranted.

A useful example of the costs of delaying market entry of competitors for biologics is adalimumab (Humira), a drug for rheumatoid arthritis and other autoimmune conditions. This drug represented the third-highest cost to government in 2013–14, costing Australian taxpayers $272.7 million. When the first biosimilar version is listed on the PBS, it will trigger a 16% statutory price reduction on all versions of the product. This means savings to taxpayers of $43.6 million in the first year (based on 2013–14 expenditure data), and with flow-on effects resulting from price disclosure likely to lead to further savings in subsequent years.

Conclusions

Pharmaceutical monopoly protections already cost the Australian health system hundreds of millions of dollars each year. US ambitions for the TPPA IP chapter in the most recently leaked draft would expand and entrench costly monopolies in Australia, with no evidence of any countervailing benefit to the Australian public.

The PPR warned that the current Australian patent system was not well designed to serve Australia’s interests. The government’s stated concern about the need to ensure the sustainability of the PBS can hardly be credible if it ignores this warning in the final stages of the TPPA negotiations.

Competing interests: Deborah Gleeson receives funding from the Australian Research Council for research on the TPPA, health and nutrition. She has received funding from various national and international non-government organisations to attend speaking engagements related to trade agreements and health, including the TPPA. She has represented the Public Health Association of Australia on matters related to the TPPA. The views expressed in this article are ours and not those of any organisation we are affiliated with.

Provenance: Not commissioned; externally peer reviewed.

References are available online at www.mja.com.au.

For debate

An incidentaloma not to be missed

A frail 92-year-old woman presented with pelvic and femoral fragility fractures after a fall. She had synchronous gross abdominal distension which was diagnosed as ascites. Computed tomography was requested to exclude malignancy before performing paracentesis.

Formal imaging showed a large intraperitoneal structure. The 4-Hounsfield unit attenuation was consistent with simple fluid. However, identification of septations, together with rim enhancement, led to a revised diagnosis of a cystic mass. The lesion measured 24 cm × 28 cm × 33 cm and, at an estimated volume of 16 L, displaced most of the abdominal and pelvic viscera. Fortunately, this was recognised before paracentesis.

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doi:10.5694/mja15.00221