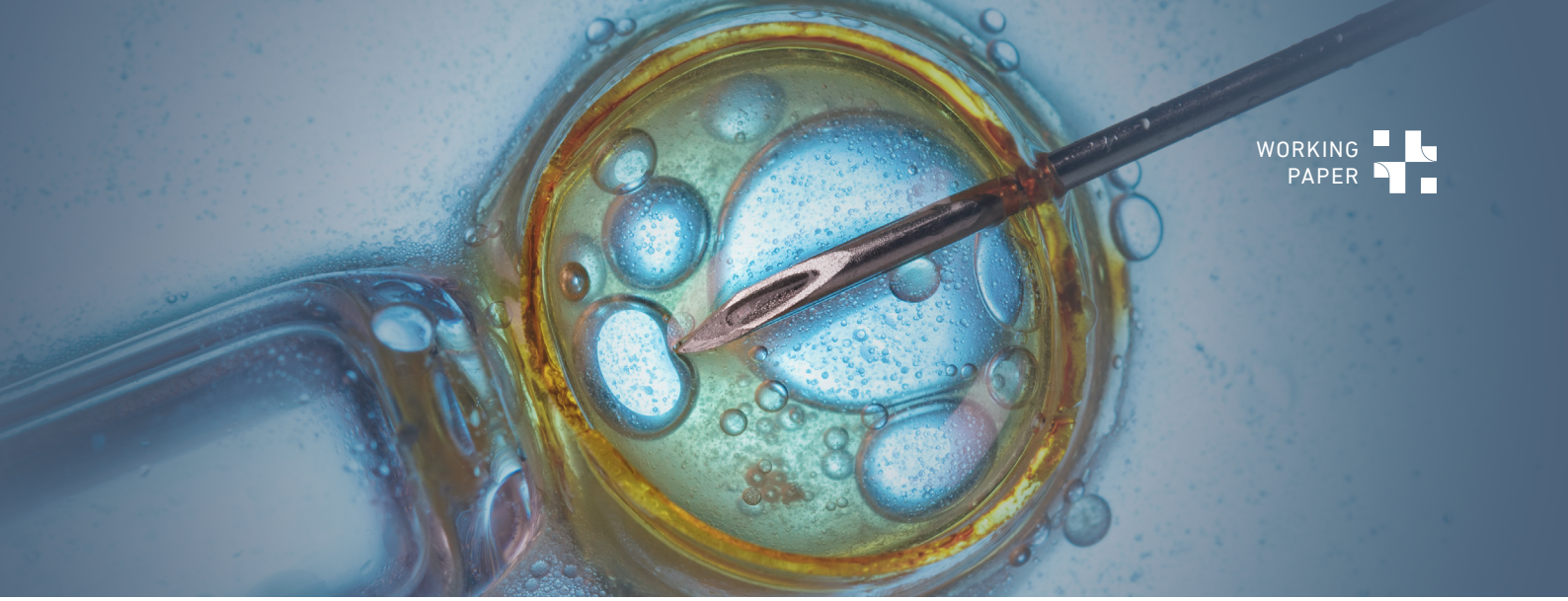

WORKING PAPER

WILL THE USMCA'S REQUIREMENTS ON REGULATORY DATA PROTECTION INCREASE SPENDING ON MEDICINES?

Evidence from Canada and Japan

Introduction

As parties to the United States-Mexico-Canada Agreement (USMCA), Canada and Mexico have agreed to adopt important intellectual property protections for biologic medicines. Most significantly, both countries have agreed to increase the term of regulatory data protection (RDP) for new biologic medicines to ten years, thereby approaching the 12 years provided by the United States. Currently, Canada provides an eight-year term, while Mexico offers no protection.

Despite past evidence to the contrary, some have suggested that this provision of the USMCA will increase drug spending. For example, a memo prepared for Canada's Health Minister suggested that the USMCA will result in additional medicine costs of CA$169m by 2029.

This research note presents evidence that extending the term of regulatory data protection is unlikely to drive up health spending beyond existing trends. Evidence from Japan and Canada, which both lengthened their respective terms of data protection unilaterally in 2007 and 2006 respectively, shows that the increased protection did not raise drug spending as a percentage of overall health care spending or lead to higher growth rates of drug spending.

The research note proceeds as follows. The first section gives an overview of methodology and data, followed by an overview of the role and rationale for regulatory data protection in the research and development of biologic medicines. The paper then presents evidence on health and medicines spending from Japan and Canada in the years immediately preceding and following the lengthening of their terms of protection for regulatory data.

This research note presents evidence that extending the term of regulatory data protection is unlikely to drive up health spending beyond existing trends.

Methodology and data

In order to determine the impact of the introduction or extension of regulatory data protection rules on medicine spending, we identified two countries (Canada and Japan) that made material changes to their regulations in this area at specific and clearly identifiable points in time. We then examined a number of trends in medicine spending compared to overall healthcare spending, from the five years preceding the change to the most recent year of available data. Where the data allowed, we additionally compared spending on patented medicines to other metrics in order to assess more clearly the impact of regulatory data protection.

Data for Canada were taken from National Health Expenditure Trends 1975-2018, compiled by the Canadian Institute for Health Information, OECD Health Spending data and Patented Medicine Prices Review Board Annual Report 2017. Data for Japan were drawn from OECD Health Spending data.

The role of regulatory data protection

Biologic medicines – complex drugs with large molecular structures – are emerging to complement traditional small-molecule, chemically-synthesised drugs.

This new era of biotechnology promises a revolution in how doctors manage and cure diseases, offering hope to patients with conditions for which there are currently no treatments. Advances in gene therapy, the development of safer vaccines, precision medicine and superior diagnostics stand to benefit millions.

Together with patents, regulatory data protection is essential to promote innovation in biologic medicines. For a limited period, regulatory data protection prevents competitors from relying on the data generated in clinical trials by the original biologic medicine developer.

Drug regulatory authorities require data from preclinical and clinical trials to be able to approve and certify that a biopharmaceutical technology is safe and effective for patients before market entry. Clinical trials are becoming increasingly costly and complicated and add significantly to the cost of developing a new medicine.

A sufficient term of regulatory data protection therefore gives biopharma innovators enough time over which they have the opportunity to recoup the costs of compiling clinical trials data, before that data is made available to biosimilar manufacturers to use in their own marketing approval applications.

The protection of clinical trial data is also important since patents alone may be insufficient to protect biologic medicines. This is because the molecular structure of biologics is far more complex than "traditional" chemically -synthesized drugs (Figure 1), making it impossible to replicate an original biologic precisely. Given that each biosimilar is slightly different from the originator, patents may offer only limited protection, as patents are granted for specific inventions and do not cover the variations that will inevitably arise in the process of developing a biosimilar.

The United States offers a 12-year term for regulatory data protection for biologics. The European Union provides 10 years. Canada and Japan each currently offer eight years of regulatory data protection for biologics, while China in 2018 proposed up to 12 years for certain biologics.

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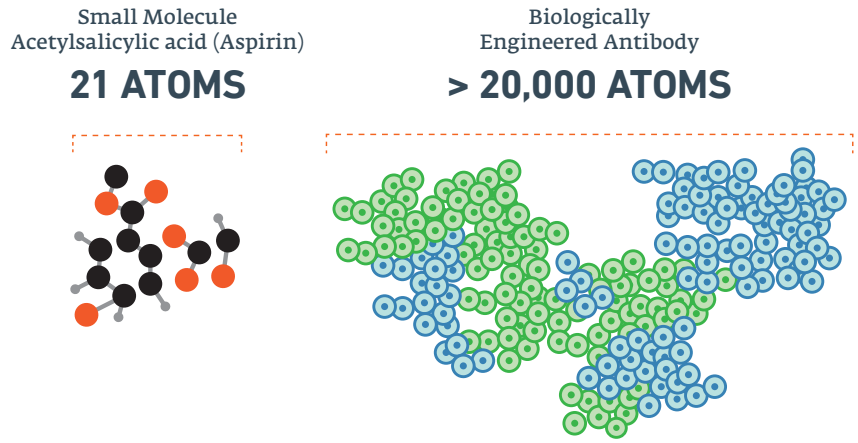

Figure 1: Biologics: bigger and more complex molecules

Source: adapted from Amgen Inc. "Biologics and biosimilars: an overview" - March 2014

Evidence from Canada and Japan

As stated in the introduction, much of the public discourse around the IP chapter of the USMCA has focused on its potential to increase spending on medicines. However, there is no evidence, or even analysis, to support such claims.

One way of assessing the impact of the introduction of higher IP standards such as regulatory data protection (RDP) on medicines spending is to look at examples in which countries introduced or modified their IP framework along these lines. Canada and Japan provide two such examples, with a clear time-point of structural change that allows comparison between the periods preceding and following the change.

In 2006, Canada increased its RDP term to eight years. The following year, Japan increased its term of RDP from six to eight years. Notably, these increased RDP terms applied to all new medicines in these countries, not just biologics as agreed in the USMCA.

The experiences of both countries, captured in the data provided below, show that drug spending as a percentage of overall health care spending did not increase, nor did growth rates of drug spending, following the introduction of longer terms of data protection.

Canada

Spending on drugs as a proportion of Canada's overall health expenditure is less today than it was in 2006, the year that regulatory data protection was introduced. In fact, drug expenditures declined as a proportion of overall health spend in the years immediately following the change. In contrast, physician costs have increased appreciably (Figure 2).

The data above must be viewed in the context of significant increases in healthcare spending that Canada has experienced (with the exception of the period between 2010-2014, following the 2009 recession). Overall healthcare spending as a percentage of GDP has increased significantly in the period since 2005, reflecting greater economic growth and available government revenues. Although Canada spent more on health care as a percentage of

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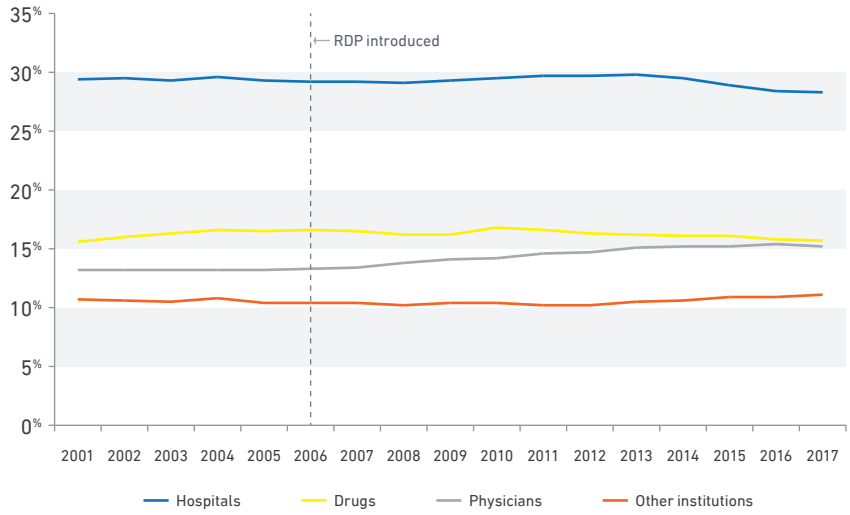


Figure 2: Distribution of total health expenditure (%) in Canada

Source: Canadian Institute for Health Information.

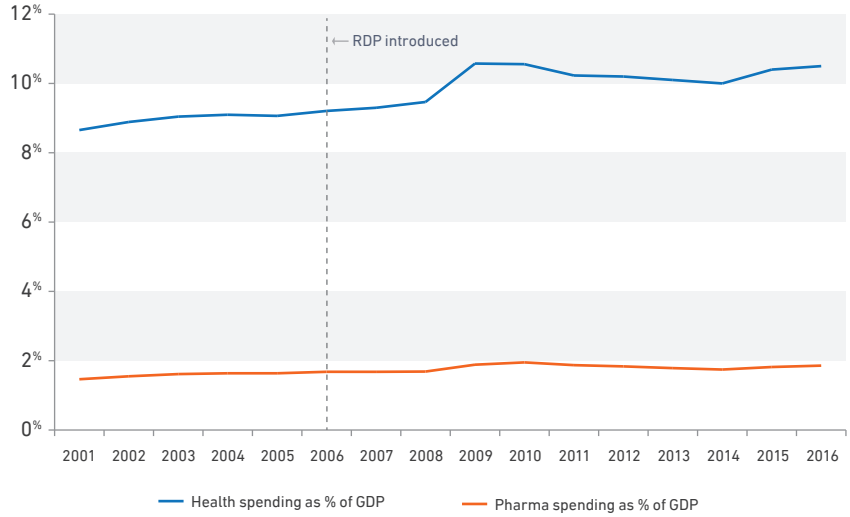


Figure 3: Canada: total health and pharmaceutical expenditures as a % of GDP

Source: OECD.

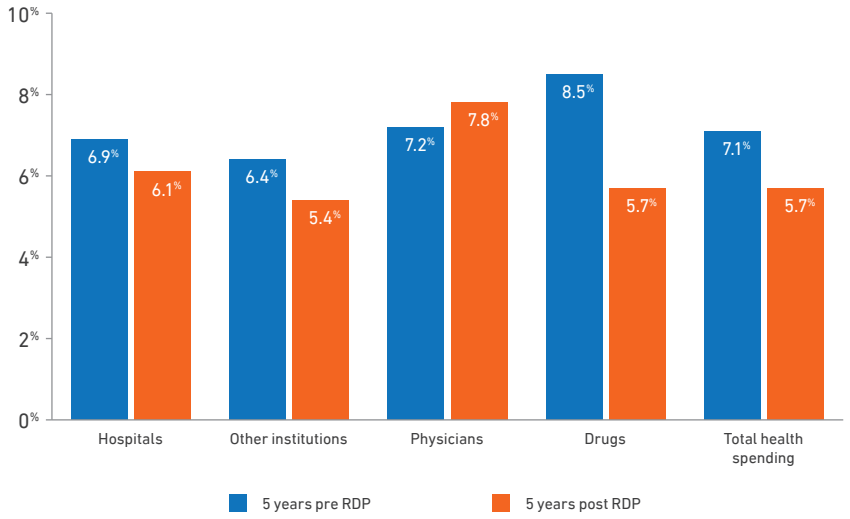


Figure 4: Canada's 5 year CAGR in healthcare expenditure, pre & post introduction of RDP

Source: Based on data compiled by Canadian Institute for Health Information.

Spending on drugs as a proportion of Canada's overall health expenditure is less today than it was in 2006.

GDP after regulatory data protection was implemented, the percentage of GDP committed to drugs has remained largely unchanged (Figure 3).

In the face of increasing total spending on healthcare, the rate of growth in medicines spending actually fell in the five years following the institution of regulatory data protection rules, at a similar rate to overall health spending. Meanwhile, the rate of growth in spending on physicians increased over the same period (Figure 4). When the most recent data up to 2018 are considered, it can be seen that drug spending growth has fallen at a faster rate than overall health spending (Figure 5).

These trends also hold true if patented medicines are isolated from overall pharmaceutical spending. According to data from Canada's Patented Medicine Prices Review Board (PMPRB), a federal government agency, the growth rate of patented medicine sales declined very rapidly in the five years immediately following the introduction of regulatory data protection in 2005 (Figure 6).

According to the PMPRB's Patented Medicine Price Index, which measures the average year-over-year change in the ex-factory prices of patented

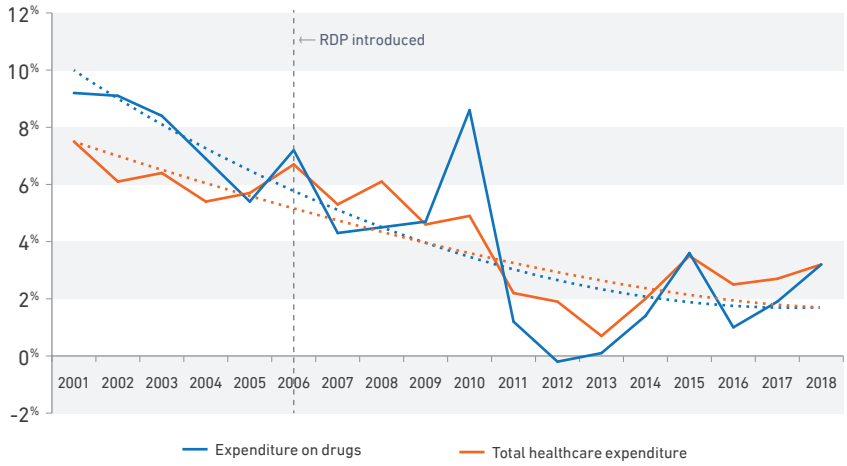


Figure 5: Canada's total expenditures on drugs, annual percentage change by year

Source: Based on data compiled by Canadian Institute for Health Information.

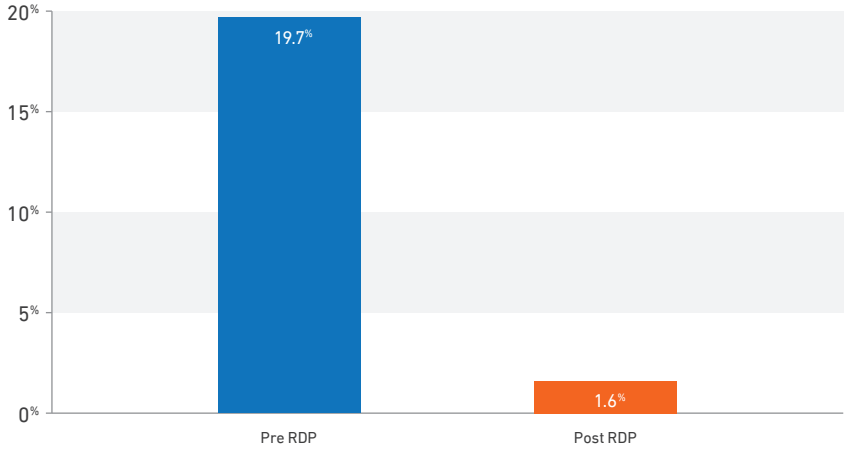
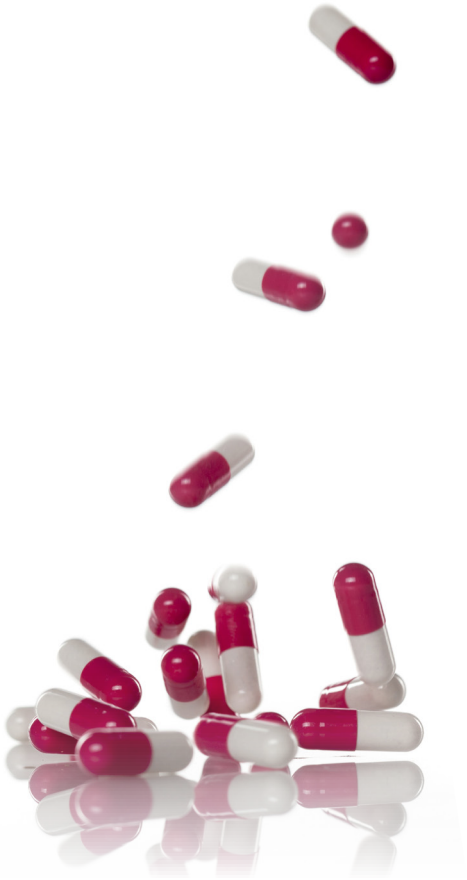


Figure 6: Canada 5 year CAGR in patented medicine sales

Source: PMPRB (2018). Annual Report 2017. Table 19. Sales of Patented Medicines, 1990 to 2017. Page 68.



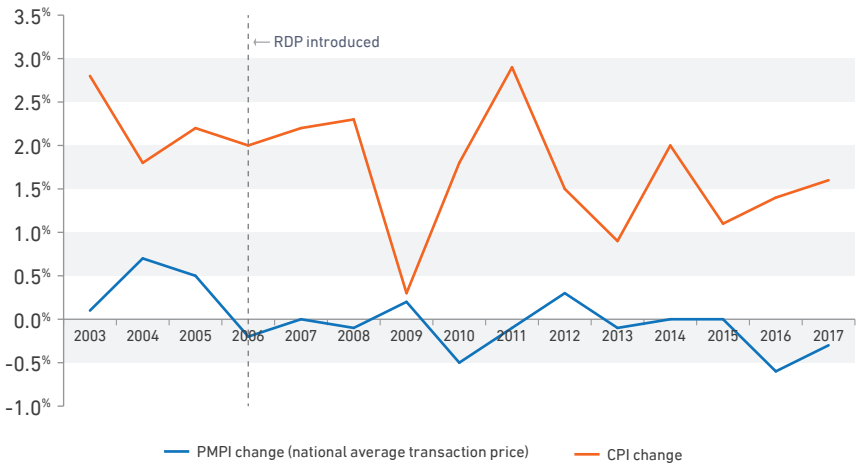


Figure 7: Canada: annual rate of change (%), Patented Medicines Price Index (PMPI) and Consumer Price Index (CPI)

Source: PMPRB; Statistics Canada.

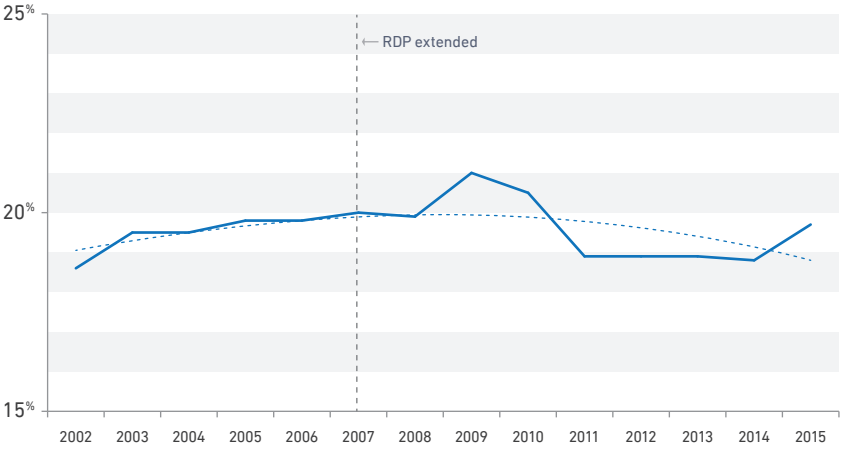


Figure 8: Japan, pharmaceutical spending as a % of total health expenditures

Source: OECD health data.

medicines sold in Canada, patented medicine price inflation has been consistently below the rate of consumer price inflation. Patented medicine prices actually underwent a period of deflation in the five years following the introduction of regulatory data protection. General price inflation, as measured by the CPI, has consistently outpaced the average increase in patented medicine prices (Figure 7), a trend that has been undisturbed by changes in Canada's IP framework.

Japan

As is the case in Canada, drug spending in Japan as a percentage of total health spending declined from 2007, when the government increased regulatory data protection from 6 to 8 years for all new medicines. Drug spending fell from 20% of total health spending in 2007 to 19.7% in 2015, the last year of available data (Figure 8).

In fact, the growth in medicines spending remained generally unchanged in the five years after 2007, when the regulatory data protection term was increased. In contrast, growth in total health spending continued to accelerate over the same period (Figure 9).

Patented medicine prices actually underwent a period of deflation in the five years following the introduction of regulatory data protection.

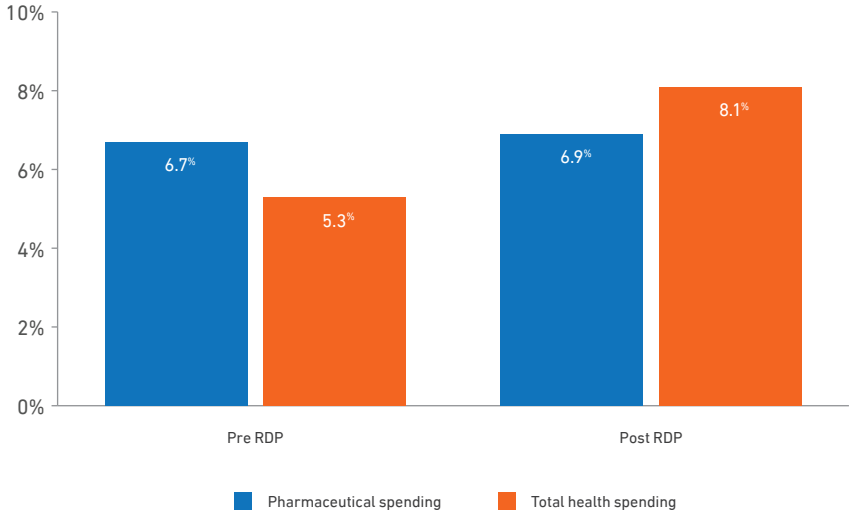


Figure 9: Japan, 5 year CAGR in total health and pharmaceutical expenditure, pre and post 2007 RDP

Source: OECD health data.

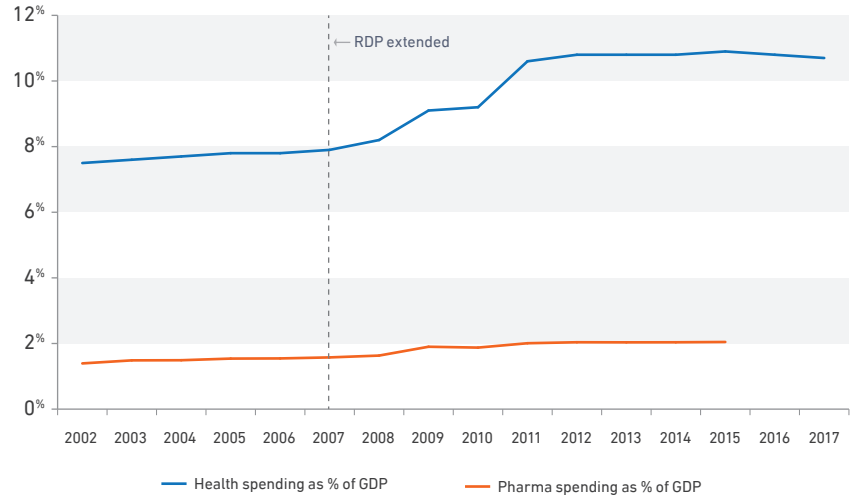


Figure 10: Japan's total health and pharmaceutical expenditure as a % of GDP

Source: OECD data.

Japan substantially increased healthcare spending as a share of GDP between 2001 and 2011, as seen in figure 10. Pharmaceutical spending as a share of GDP increased over the same period, including after the introduction of a longer term of regulatory data protection, but at a much slower absolute rate (Figure 10).

Conclusion

Given the growing importance of biologic medicines, the protection of regulatory data will become an increasingly important intellectual property right to foster innovation in healthcare. Past evidence from countries that have introduced this shows that it is unlikely to increase existing growth rates of spending on medicines, increase drug spending as a percentage of overall health care spending, or increase the price of patented medicines.

About the author

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Endnotes

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10. Canada's 5-year data protection term was made ineffective by a 1998 Federal Court interpretation of regulations. Bayer Inc. v. Canada (Attorney General), 84 C.P.R. (3d) 129, aff'd 87 C.P.R. (3d) 293, leave to appeal to SCC refused, [1999] S.C.C.A. No. 386. The Federal Court held that RDP protection in Canada was not triggered if a generic applicant could demonstrate bioequivalence without requiring the Health Minister to consult the data submitted by the innovative company
11. Japan's system prevents filing applications for follow-on approval for eight years after the innovator's approval. An additional year after that is required for the regulatory approval process to conclude.