AUSTRALIA'S MEDICINE SUPPLY

IS OUR HEALTH A NATIONAL SECURITY / RESILIENCE ISSUE ?

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Australia's Medicine Supply

An estimated 9 million Australians take prescription medicine every day, and many more use over-the-counter medications such as paracetamol and vitamins.[1]

Where do these medicines and medications come from? What quality control and testing are they subjected to? And does it actually matter where they come from, as long as they are on the shelves of our local pharmacies whenever we need them, and at a reasonable cost?

Australia is at the end of a very long global supply chain which makes the nation vulnerable to supply chain disruptions. Australia's Therapeutic Goods Administration (TGA) acknowledged these supply chain risks in 2019[2], when it noted the following:

- Australia accounts for only 2% of the global pharmaceutical market and imports over 90% of medicines. At times there may not be enough of a specific medicine in the Australian marketplace, leading to potential weaknesses in supply.
- Medicine shortages have become an increasing problem over recent years. The cause of medicine shortages is a complex and diverse interaction of many factors. Some medicines imported to Australia are only manufactured at one location, even if they are supplied by many companies. Other medicines may be manufactured in multiple locations but supplied by only one company.
- This makes Australia particularly vulnerable to medicine shortages arising from factors outside our control. These factors can include manufacturing problems, difficulties in procurement, political instability, pandemics, another global economic crisis and a range of natural disasters.

A growing number of Australians check the labels on the food they buy for themselves, and for their pets, and therefore generally know the country of origin of the product. Check the label of the medicine you take … can you see where it was manufactured? Sometimes yes, often no. Can you see where the ingredients were made? Usually no. Is there a good understanding of our medical supply chain? No.

In 2018, Australia imported US$8.33B of pharmaceuticals, comprising over 90% of the medicine consumed in country.

Most of us would be surprised to learn that China is fast becoming one of the leading manufacturers of pharmaceuticals and the active pharmaceutical ingredients (commonly referred to as APIs) that go into medicines. Some of those APIs are produced in one location then exported to other countries to be turned into finished medicines. These medicines are then imported into Australia after journeying around the world. A significant problem is that there is no publicly available information on where the ingredients of critical medicines originate. Pharmaceutical companies consider such information to be proprietary. We therefore cannot assess the resilience of our medicine supply chain.

It is worth pointing out that the aim of this paper is not to sound alarm bells about China produced medicines per se. Rather, the alarm bells should be sounding about vulnerable and opaque supply chains which have single points of failure. Any supply chain that relies on only one point of manufacture for critical products is vulnerable - regardless of where that single point of supply is located.

Many Australians would not be aware of the TGA website listing of medicine shortages; the Therapeutic Goods Act 1989 was amended effective 1 January 2019 to introduce a mandatory reporting scheme for medicine shortages and permanent discontinuations of supply of mostly prescription medicines. At the end of Jan 2020 the TGA reported 63 drugs as 'critical shortages' and 13 anticipated to go into short supply. This is incredibly

useful information which would explain to people why, from time to time, regularly consumed medicines are not on the pharmacy shelves as expected.

But, what are we doing about the shortages and could they become worse? The Coronavirus is an example of a situation that could arise with little warning, and one that could significantly impact the global medicine supply chain given the global dependencies on China's pharmaceutical industry.

On 5 December 2019, the TGA website reported that all EpiPen Jr supplies in Australia had run out.

The EpiPen Jr Shortage Example

Since 2017 Australia has experienced two episodes of significant shortages of the life-saving EpiPen Jr (used to treat severe allergic reactions in small children) as a result of overseas manufacturing issues and subsequent delivery delays. Media reporting in both instances was highly critical. Stressed and anxious parents told of their feelings of helplessness and fear.

In both instances, parents of children with allergies were advised to use out-of-date or contaminated EpiPens in an emergency.

On 2 December 2019 the TGA published advice on their website as follows:

> 'Due to the critical nature of the ongoing EpiPen Jr shortage, the TGA is allowing one batch to be supplied that has not met all the required quality specifications… Several batches of Epipen Jr have been found to be affected by very low-level contamination with another medicine, pralidoxime… In the situations in which EpiPen Jr is used, administration of adrenaline can be life-saving. The risk from not having adrenaline available to treat anaphylaxis is far greater than the risk of being exposed to a very small amount of pralidoxime.'

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On 13 December 2019, the TGA reported that stock of the new batch of EpiPen Jr supplies, the conditionally released batch (i.e. with pralidoxime contamination), had arrived in Australia and would be dispatched to wholesalers and available for delivery to pharmacies before the end of the year.

Is it any wonder that the ABC reported on 4 December 2019 that doctors and groups representing patients have demanded an alternative supply of this life-saving drug?

In 2017, The Society of Hospital Pharmacists of Australia found the five most common therapeutic classes of medicines regularly in short supply in Australia were antibiotics, anaesthetics, cardiology drugs, endocrinology drugs and chemotherapy. These are all extremely important medications that are used in huge quantities throughout the world every day.[3]

Given the lack of publicly available information in Australia related to our medicine supply chain, it is useful to look at the following US analysis.

Is There a US Pharmaceutical 'Crisis' ?

On 31 July 2019 the US Government's *US-China Economic and Security Review Commission*[4] held a public hearing on 'Exploring the Growing US Reliance on China's Biotech and Pharmaceutical Products'. The testimony from the 10 witnesses, both their written submissions and personal appearances before the Commission, made for sobering reflection.[5]

The Commissioner noted in his opening to the hearing that: 'China has emerged as the second largest pharmaceutical market in the world by revenue only behind the United States. There are several factors contributing to China's attractiveness as both a market and a production site including the low cost of production, a large consumer base, and a deep talent pool. And as China's market power continues to expand, US consumers are becoming increasingly reliant on drugs sourced from the country which presents economic and national security risks …

The establishment of this Commission in October 2000 indicates that the US sees the economic relationship with China through a national security lens. **Economics do not override national interest and national security.**'

As China's market power continues to expand, US consumers are becoming increasingly reliant on drugs sourced from the country which presents economic and national security risks ...'

The US reliance on Chinese pharmaceuticals has become a risk to national security. Key observations from the testimony at the 31 July 2019 hearing support this assessment. For example:

- Nearly all pharmaceuticals (almost 90%) taken by Americans are generics, most of which are imported from China or India.
- The US indigenous drug manufacturing capability has decreased significantly because of rising costs and deliberate market manipulation by the Chinese. Most active pharmaceutical ingredients (APIs) are imported from China or India, with India actually sourcing a large number of inputs from China.
- The growing reliance on Chinese imported pharmaceuticals and APIs is placing at risk the health security, and therefore the national security, of the US. It is a complicated problem and requires a coordinated approach entailing economic, health, security and diplomatic considerations.
- The quality and testing regimes of drugs and APIs manufactured in China are assessed as substandard. There are allegations of deliberate falsification of data and no formal mechanisms for testing or monitoring standards of Chinese APIs used in the US.
- The US Food and Drug Administration (FDA) frequently is hampered by Chinese resistance and regulatory barriers in its efforts to undertake the necessary inspections and quality control of Chinese drug manufacturing. Substandard drugs therefore are entering the US market.

- Supply chains are not understood, vulnerabilities are not fully understood, no one agency seems to have responsibility or accountability.

The Commission's annual report to Congress, submitted in November 2019, summed up the implications for the United States as follows:

- 'Nurtured by subsidies and protected from foreign competition, China's pharmaceutical companies have emerged as preeminent manufacturers of pharmaceuticals and their ingredients. This presents a direct threat to US competitiveness and national security … China's lax regulations put every US consumer taking medicine imported from China, or made with Chinese APIs, at risk…'
- 'US dependence on drugs from China exacerbates the risk of drug shortages … If China were to cut off its supply of drugs or APIs to the United States, it could lead to a public health crisis…'

In October 2019, the Health sub-committee of the *US Congressional Committee on Energy and Commerce* began public hearings to further assess the risks to the US of reliance on overseas manufacturing of critical pharmaceuticals, including APIs and finished drug products. The Legislative Hearing, *Safeguarding the Pharmaceutical Supply Chain in a Global Economy,*[6] had bipartisan support.

The Democrat Chair of the hearing in her opening statement made the following, impassioned, comments:

- 'There is a hidden health care crisis in this country that will affect us all: the crippling inadequacy of the American drug supply.
- '… an over reliance on foreign production for critical medication which is a national security risk. China globally dominates the manufacturing of active pharmaceutical ingredients, and China has gained a chokehold over the global supply of penicillin … Beijing could use US dependence for critical drugs as an economic weapon and exploit the health and safety of our armed forces and the American public. This is a threat to our nation's security.

The ranking Republican on the Committee expressed similar concerns in his opening statement: 'The United States reliance on overseas manufacturing not only raises quality concerns, but it also poses national security risks as well … reliance on foreign suppliers, particularly in those countries with which we have unstable relationships, poses an increased risk to Americans.'

Concerns regarding US national security were further stated when the US Defense Health Agency (DHA) Operations Directorate, told the *US-China Economic and Security Review Commission* that they were concerned about any situation where foreign actors, such as China, could control access to critical warfighting material. The Directorate believed there would be a potential serious risk to the US military if there were interruptions in the pharmaceutical supply chain. The Commissioners were told by the DHA that 'when we focus on readiness … we should not be solely focused on the cost.' The DHA further made the point that 'the national security risks of increased Chinese dominance of the global API market cannot be overstated …'

Dr Rosemary Gibson, author of *China Rx* and a strong advocate for rebuilding domestic pharmaceutical capabilities noted that "All it takes is one plant to shut down to cause a global shortage." With respect to the concentration of global production in China she warns that "If you have a supply chain concentrated in a single country, no matter what country it is, that's a risk of epic proportions."[7]

China also produces a significant portion of the world's supply of personal protective equipment, such as face masks and respirators; a category of supply that has been significant for the Coronavirus and for the Australian bushfire disaster of the summer of 2019/2020.

US Congressional legislation changes are anticipated in 2020.

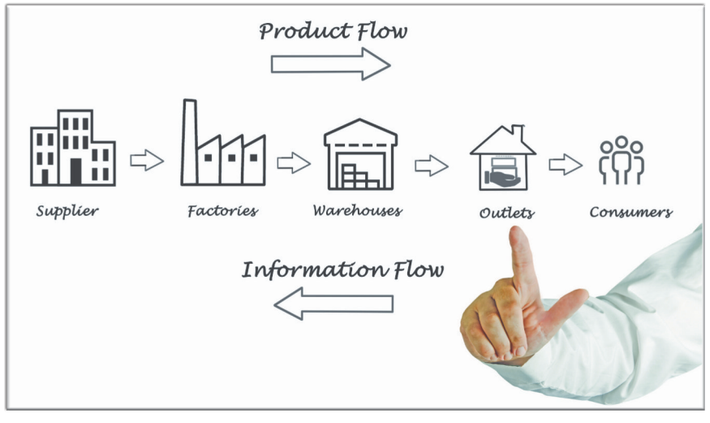
What Does The Medical Supply Chain Look Like?

It is difficult to fully analyse Australia's medicine supply chain risks given the limited information available to the public. Unfortunately that is not a problem confined just to Australia. As was noted by the US Government's US-China Economic and Security Review Commission, supply chains are not understood, vulnerabilities are not fully understood, no one agency seems to have responsibility or accountability.

Given that the US is the No. 1 country from which Australia imports pharmaceuticals, it is worth reviewing their supply chain. However, **what is clear is that the US is having considerable difficulty analysing its own medicine supply chain:**

- A significant issue is the apparent lack of an entity in the US Federal Government that is accountable for knowing who controls the US medicine supply. According to Michael Wessel, a Commissioner on the US Government's US-China Economic and Security Review Commission, the US simply does not know enough about China's pharmaceutical sector, yet most APIs are imported from China or India, with India, in turn, actually sourcing a large number of inputs from China.
- The FDA Center for Drug Evaluation and Research stated at a US Congressional hearing that they cannot determine with any precision the volume of APIs that China is actually producing, or the volume of APIs manufactured in China that are entering the US market.[8]
- A lack of understanding, combined with the evidence presented to the Commission that the quality and testing regimes of drugs and APIs manufactured in China are assessed as substandard, results in a lack of confidence in this major component of the US supply chain. This is particularly of concern given that US imports 95% of ibuprofen and between 40 and 45% of penicillin supplies from China. China is also the largest manufacturer of vaccines in the world – about 20% of the global supply.
- One of the big unknowns is how many products are sole-sourced—in which literally only one place in the world makes that raw material. This lack of information is a major concern. Michael Ganio, director of pharmacy practice and quality at the American Society of Health-System Pharmacists raises similar concerns "What is the threat to our national health care if there is some kind of geopolitical issue or an outbreak like this or some kind of natural disaster? **We really don't know.** "[9]

The US is the No. 1 country from which Australia imports pharmaceuticals - *if they don't understand their supply chain then the chance of Australians understanding our own is low.*



How Do Other Countries Address The Issue?

Information on other nations' medicine imports is not readily available to the public. Examples are:

United Kingdom - As at December 2019, 90% of UK medicines are imported, and of that number 45% come from the EU. India is the global leader in generic drug production and manufactures 25% of all medicines in the UK.

India - India's generic drug industry depends on China for 80% of APIs and chemical intermediates essential for production. The increased Indian dependence on the import of active pharmaceutical ingredients (APIs) from China has raised national security concerns in India.

Japan - Imports of foreign pharmaceuticals accounted for approximately 30 percent of the total Japanese market in 2018.

The Finland Example

Finland is a small, wealthy nation, far to the north of Europe, part of NATO, and with Russia on her doorstep. Like most nations, there are strategic stockpiles of key drugs and hospital supplies for what the Ministry of Defence calls 'disruptive situations' and 'exceptional circumstances'.

The Finnish government has recognised that these stockpiles are becoming increasingly reliant on imports and they see this as a risk to national security. The Finnish Security and Defence Policy at Section IV: *Precautionary Measures and Combating Threats to Society*, states that the ongoing stockpiling is essential to ensure the operation of hospitals during 'disruptive situations' and 'exceptional circumstances', but that efforts to establish alternative sources of these supplies must be continued.

Further, the government recognises that the restructuring of the pharmaceutical industry may have a detrimental effect on Finland's security of supplies in the future, especially as Finland is ceasing production of infusion fluids and vaccinations. The government concludes that international cooperation in ensuring security of health care supplies is increasingly important.

A globalised pharmaceutical system presents a new set of security risks for many nations, but particularly those with long supply lines.

Finland recognises this risk and acknowledges that options need to be explored to mitigate future vulnerabilities.

Does Australia Have A Problem?

Australians, at the end of a very long global supply chain, and situated on the rim of a volatile Asian region, should be worried about their health and the safety and availability of the medicines they consume. Given that we import over 90% of our medicines, the time is right for the Australian Government to follow the lead of the US Congress and conduct a thorough and public analysis of the resilience of our medicine supply chain. A global health crisis such as the Coronavirus can escalate unexpectedly and rapidly. The problem is that we do not know how significant that problem is, or could become.

The health and well being of Australians is a national security / resiliency issue and one that needs to assessed for risks and vulnerabilities just like every other aspect of national security from energy to the economy to the environment to the military.

Australia's supply chain for the entire range of healthcare products is incredibly complex. There are, of course, national and international regulatory frameworks to ensure quality and ongoing supply. However, these were set up more than three decades ago. Are they still fit for purpose?

Pharmaceuticals consistently rank inside the top 10 of Australian imports. The US is the number 1 nation from which our medicines are imported. There are clearly risks to Australia's national security that need to be examined in light of the issues identified to Congress by the *US-China Economic and Security Review Commission.*

Do we Australians know where the medicines we take every day are manufactured? Should we care? Do we understand the fragility of the global supply chain that brings these medicines to our local pharmacy? And do we realise that our local pharmacies run a just-in-time approach to their inventories making all of us vulnerable when stock shortages occur?

The TGA is in the final phase of a transition to new labeling requirements for medicines which will mandate certain information on labels from 1 September 2020. For all prescription and non-prescription medicines, all APIs, and the quantities and proportions of them, must be listed clearly on labels. However, t**he new legislation does not mandate information about country of origin or the manufacturer of any of the ingredients,** only that the name and contact details of the product sponsor or distributor be included.[10] Why not?

The TGA is in the final phase of a transition to new labeling requirements for medicines; however, it does not mandate information about country of origin nor the manufacturer of any of the ingredients.
WHY NOT ?

Who tests the medicines Australians consume every day? The TGA conducts limited sample testing (around 2000 products per year.) The TGA has significant testing capacity that it could scale up if there was a need, but there is very limited regulatory requirement to routinely test the quality of pharmaceuticals manufactured in or supplied to the Australian market.

Over recent years, the TGA has made progress in investing in capacity to test, but as it currently stands, the only products that are routinely batch tested are biological medicines - vaccines, insulin and other blood products. The vast majority of medicines consumed in Australia are not subjected to routine pharmaceutical quality testing by the TGA, with adequate quality assumed based on Good Manufacturing Principle product certification. This latter assumption may need to be revisited given the *US-China Economic and Security Review Commission* observation that the quality and testing regimes of drugs and APIs manufactured in China are assessed as substandard. There are allegations of deliberate falsification of data and no formal mechanisms for testing or monitoring standards of Chinese APIs used in the US. As the US Congress heard from witnesses to the 31 July 2019 inquiry, the FDA is regularly thwarted in its efforts to inspect and certify manufacturers outside of continental US boundaries ...we largely rely on the US FDA to 'certify' many of the pharmaceuticals we import.

Australia's National Medical Stockpile

Australia, like most nations, holds a national medical stockpile, however this is largely to deal with national public health emergencies such as influenza pandemics and biological, chemical or radiological incidents. The Federal Government's 2019-2020 Budget specifically allocated funding to:

- ' … improve the operation of the National Medical Stockpile to ensure Australia is well prepared for a national public health emergency. New arrangements will be implemented, including the distribution of the Stockpile's inventory around several locations across the country, and improved arrangements around storage, maintenance and transportation of the specialist medicines in the Stockpile.
- 'Improving how the Stockpile operates will benefit all Australians who require immediate and potentially life-saving medicines and treatment that only the Stockpile can supply in an emergency.'

While the national stockpile will be essential to protect Australians during a national health emergency, it will do little to help on a day-by-day basis if supply chains break down, if national distribution networks falter, if pharmaceuticals are contaminated or if the local pharmacy or hospital run out of something.

Australia's Indigenous Medicine Manufacturing Capability

Australia has extremely limited and diminishing manufacturing capacity across all sectors of products apart from vaccine manufacture. There are some smaller industries with capacity for niche markets; however, government price regulation around the Pharmaceutical Benefits Scheme has forced the large majority of off-patent product manufacturing, where the vast majority of life-saving medicines sit, off-shore. As a benchmark, Australia has almost no capacity to manufacture any active pharmaceutical product for most of the products listed on World Health Organisation's list of Essential Medicines.

Australia's Supply Chain Resilience

In 2015 Infrastructure Australia identified the need for a national freight and supply chain strategy and the Australian Government agreed that such a strategy was necessary. Accordingly, in conjunction with the Council of Australian Governments (COAG) Transport and Infrastructure Council, a strategy was developed in 2019. However the global supply chains that bring the freight to move around Australia, including pharmaceuticals, were not part of the assessment.

Of particular concern, and noted above, is the just-in-time nature of those supply chains. While just-in-time makes sound business sense, it makes Australians vulnerable to disruptions in the supply chain, be they inadvertent or deliberate. Furthermore, single-source distribution points in Australia are especially vulnerable and the flow-on effects of a disruption could be significant, especially when time and temperature sensitive medicines are being moved around the country.

The primacy of the market and successive government's market-based approach to managing society and the economy, should not dominate the policy framework when it comes to the health and wellbeing of Australians. The market does not put citizens and national security at its centre. Australia has become a nation obsessed with driving prices down across all aspects of life. Yet **the lowest cost can come at a high price, and that is the undermining of Australian's resilience as a nation and risks to our national security on many levels.** In so many other areas fundamental to the Australian way of life, cost reductions and the unimpeded function of the 'market' go unquestioned.

What Could We Do In Australia ?

While it is not practical for Australia to become fully self-reliant, perhaps the resilience that would be provided by a level of indigenous, or more appropriately called 'sovereign', capability needs to be determined.

Such an understanding would require a nation-wide assessment of the critical medicines without which Australians would suffer significant health consequences. These are the consequences that could impact on a day-to-day basis in homes, at the doctor's surgery and hospitals – not the events for which the national stockpile exists to mitigate.

Our biggest vulnerabilities as a nation are the intersections and interdependencies in the systems that support us in this country from local to global levels. The blind trust in the market approach to governance, risk and resilience that has captured successive Australian Governments has, at the core, a drive to the lowest cost. If we do not ask what that lowest cost really means for our national resilience, then we are have going to serious problems as a society.

On the issue of lowest cost, it is worth remembering that Australian political leaders have a history of bipartisanship when it comes to funding and arming the Australian Defence Force (ADF). Cheap is not an option as evidenced by decisions regarding the Joint Strike Fighter and the future submarines. Yet in so many other areas fundamental to the Australian way of life, cost reductions and the unimpeded function of the 'market' go unquestioned. The importation, certification and distribution of pharmaceuticals is just one such area.

Several of the recommendations from the US Congressional Commission report are worthy of consideration in determining how to address the growing risks to Australia.

As a first step, the Commission recommended that: 'Congress hold hearings assessing the productive capacity of the US pharmaceutical industry, US dependence on Chinese pharmaceuticals and active pharmaceutical ingredients (APIs), and the ability of the US Food and Drug Administration (FDA) to guarantee the safety of such imports from China.'

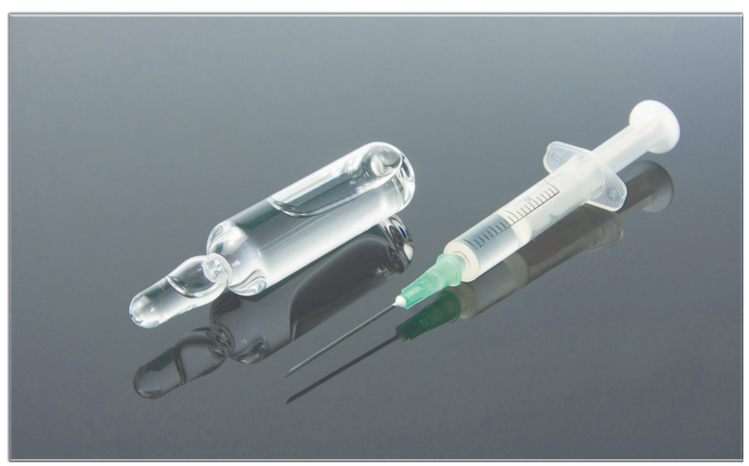
- *The Parliamentary Joint Standing Committee on Foreign Affairs Defence and Trade could be an appropriate Australian Government entity to undertake a similar initial assessment regarding our **overall** pharmaceutical import dependencies and risks.*

Another significant issue that arose from the US Congress Commission hearings was that of the dependence of the US Armed Forces on medicines imported from China, as discussed previously.

- *Could there be a similar risk to the men and women in the ADF from many of the same pharmaceutical threats that were explored in the US at the Congressional hearing? The ADF relies on Australia's civilian pharmaceutical industry and civilian freight systems to manage the flow of necessary medicines and other medical support products. It is unclear what, if any, collaboration occurs between Australia's pharmaceutical industry, the TGA and the ADF to discuss or set the parameters for the security of supply of pharmaceuticals, particularly those that might be necessary for use in operations or for a deployed force. What is clear, however, is that some kind of engagement, collaboration, and joint planning should be occurring.*

The Commission also recommended that the Congressional hearings should work towards enacting certain legislation to improve national health and security outcomes. The recommendations for legislation that could be pertinent for Australia to consider further for adaptation for the Australian case are:

- Require the FDA to compile a list of all brand name and generic drugs and corresponding APIs that: (1) are not produced in the United States; (2) are deemed critical to the health and safety of US consumers; and (3) are exclusively produced—or utilize APIs and ingredients produced—in China.
  - *In the case of Australia, the Government could consider amendment to the TGA labeling standards to adopt country of origin /manufacture information*
- Require Medicare, Medicaid, the US Department of Veterans Affairs, the US Department of Defense, and other federally funded health systems to purchase their pharmaceuticals only from US production facilities or from facilities that have been certified by the FDA to be in compliance with US health and safety standards and that actively monitor, test, and assure the quality of the APIs and other components used in their drugs, unless the FDA finds the specific drug is unavailable in sufficient quantities from other sources.
  - *The sourcing of ADF medicines could be addressed in a similar manner.*
- Require generic drug manufacturers that sell medicines to the US Department of Defense and US Department of Veteran Affairs to disclose which essential drugs are at risk of shortage or supply disruption because the relevant products, active pharmaceutical ingredients, chemical intermediates, and raw materials contained in them are sourced from China.
  - *The sourcing of ADF medicines could be addressed in a similar manner.*
- Requiring drug companies to list APIs and their countries of origin on labels of imported and domestically produced finished drug products.
- Creation of a risk-based system making importers of APIs and finished products liable for any health risks incurred by consumers in the event the product is proven unsafe due to contamination, mislabeling, or other defects. Special attention should be paid to finished drug products imported from China or containing APIs sourced from China.



Conclusions

Australia imports over 90% of medicines and is at the end of a very long global supply chain making the nation vulnerable to supply chain disruptions. The TGA has acknowledged these supply chain risks when they report that at times there may not be enough of a specific medicine in the Australian marketplace, leading to potential weaknesses in supply.

Australia is particularly vulnerable to medicine shortages arising from factors outside our control. These factors can include manufacturing problems, difficulties in procurement, political instability, pandemics, another global economic crisis and a range of natural disasters. The current Coronavirus emergency is an example of this.

Our understanding of our medicines supply chain is rudimentary. The US Commission hearings have highlighted that even the US, our largest source of medicines, does not have a robust understanding of its supply chains, its vulnerabilities are not fully understood and no one agency seems to have responsibility or accountability. They have concluded that an over reliance on foreign production for critical medication is a national security risk. We would be foolhardy to think that our situation is any less risky.

Recommendation

While it is not practical for Australia to become fully self-reliant, perhaps the resilience that would be provided by a level of indigenous, or more appropriately called 'sovereign', capability needs to be determined. Sovereign capability infers not only a manufacturing capability, but the appropriate research and development facilities and a skilled workforce.

We need to have a robust analysis of our medicine supply chains and the Government needs to address any shortfalls in our national resilience before a crisis occurs. Sadly, we may already be too late ...

Endnotes:

1. Health Direct Blog, *Take Medicines Seriously*, 22 August 2018 https://www.healthdirect.gov.au/blog/take-medicines-seriously

2. https://www.tga.gov.au/sites/default/files/consultation-reforms-generic-medicine-market-authorisation-process.pdf *Reforms to the generic medicine market authorisation process*, Consultation paper section *Need for a Robust Supply of Medicines in Australia*, Version 1.0, February 2019

3. http://hospitalhealth.com.au/content/clinical-services/article/when-medicines-run-dry-what-s-your-backup-plan--1545305922#ixzz6CmOfGgp4

4. The US-China Economic and Security Review Commission was created by the US Congress in October 2000 with the legislative mandate to monitor, investigate, and submit to Congress an annual report on the national security implications of the bilateral trade and economic relationship between the US and the PRC, and to provide recommendations, where appropriate, to Congress for legislative and administrative action. https://www.uscc.gov/about

5. All testimony extracts and statements from the 31 July 2019 US-China Economic and Security Review Commission hearing, *Exploring the Growing US Reliance on China's Biotech and Pharmaceutical Products,* can be accessed at: https://www.uscc.gov/sites/default/files/2019-10/July%2031,%202019%20Hearing%20Transcript.pdf

6. House Committee on Energy and Commerce, Health sub-committee, public hearing 30 October 2019, *Safeguarding the Pharmaceutical Supply Chain in a Global Economy*, statements and testimonies https://energycommerce.house.gov/committee-activity/hearings/hearing-on-safeguarding-pharmaceutical-supply-chains-in-a-global-economy

7. Dr Rosemary Gibson quoted in Wired.com 28 Jan 2020, https://www.wired.com/story/the-coronavirus-is-a-threat-to-the-global-drug-supply/

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9. Ibid.

10. TGA Recommendations and Guidance on the new labeling legislation: https://www.tga.gov.au/book-page/3-recommendations-and-best-practice

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