Challenges Associated with Globalisation of The World's Pharmaceutical Supply Chain and Australia's Lack of Sovereign Pharmaceutical Manufacturing Capability

Recent global events triggered by the COVID-19 pandemic have highlighted the challenges associated with globalisation and the resulting fragility and opacity of the world's pharmaceutical supply chain. Founded in 1975, IDT Australia Limited (Institute of Drug Technology, IDT) is an Australian pharmaceutical manufacturer specialising in the development and manufacture of small molecule Active Pharmaceutical Ingredients (APIs)[1] and Finished Dosage Forms (e.g. tablets, capsules, injectable products).

Small molecule drugs (drug products derived from chemistry as opposed to biological processes) comprise the majority of the medicines we consume, representing over 78% of total market share.[2] Over the course of IDT's history, the Company has witnessed firsthand the movement of the manufacture of active pharmaceutical ingredients, closely followed by finished drug products, from countries such as Australia and the United States of America (U.S.), to India and China. In the U.S. over 90% of its medicines are generic products which are now imported from India and China, with India importing in excess of 80% of its APIs (to be manufactured into those generic drug products) from China.[3] Australia also sits at the end of a very long and often opaque supply chain, importing over 90% of its medicines.[4]

The COVID-19 Pandemic Severely Disrupted Global Pharmaceutical Supply Chains

Early in the COVID-19 crisis the banning of exports of certain APIs and finished drug products by India[5] (to prioritise supply for its own people), the disruption of Chinese manufacturing and the delays associated with procurement and freight created critical shortages in global drug supplies. The recent disruption to pharmaceutical supply chains highlights a fundamental sovereign risk associated with the outsourcing of Australia's drug manufacturing to other countries. In the same way a country needs to be able to defend its borders and feed its people, IDT believes that access to medicine is of sovereign importance.

IDT's own experiences during the crisis are perhaps worth considering. Early on in the crisis, IDT was tasked by the Australian Government to secure the supply of API and/or finished dosage form of a particular medicine for the Australian people. The medicine was not one which is kept in Australia's National Medical Stockpile. IDT set about the task of looking into in-house API synthesis whilst also (as part of a working group) reaching out worldwide to its global API and finished dosage form supply contacts. An Australian finished dosage form manufacturer was on stand-by to receive API and convert it into finished drug product; but without the API starting material they could not manufacture the medicine. By the end of the first week of IDT's efforts to manufacture or source this particular medicine, the number of COVID-19 cases in Australia had almost tripled. IDT's in-house synthesis of the API would take time, and the working group was yet to source a milligram of API or a single tablet of finished drug product.

IDT's interactions with Government throughout this crisis were excellent. The Government were highly responsive and the individuals IDT liaised with were working around the clock to rise to the challenges Australia faced. Despite these efforts, the speed at which certain elements of Australia's outsourced pharmaceutical supply chain broke down highlight systemic issues which need to be addressed. Australia should learn from this situation and be better prepared next time.

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[1] Active Pharmaceutical Ingredient (API), is the term used to refer to the biologically active component of a finished dosage from. Other ingredients are commonly known as Excipients which are inactive substance(s) formulated alongside the API of a medication, for the purpose of bulking-up formulations.
[2] Cited electronically at: https://resultshealthcare.com/insight/cmo-sector-2020-current-trends-and-future-prospects-white-paper/
[3] Cited electronically at: https://www.australiandefence.com.au/news/does-australia-have-a-medicine-supply-problem
[4] Cited electronically at https://www.jbcs.co/iieraust/
[5] Cited electronically at: https://dgft.gov.in/sites/default/files/Noti%2050_0.pdf

Inquiry into the implications of the COVID-19 pandemic for Australia's foreign affairs, defence and trade

Australia's Pharmaceutical Supply Chain Post COVID-19

The challenges faced by Australia's ability to procure critical supplies during the COVID-19 crisis also provides an opportunity for Government to reprioritise the factors it assesses in relation to sovereign risk, and refining and improving health policy and pharmaceutical procurement. While cost is an important consideration, prioritisation of continuity of supply, quality and timeliness of response to unforeseeable events would mitigate the impact of events such as the COVID-19 pandemic. Given that small molecules make up approximately 80% of medicines we take, it seems appropriate for Australia to have increased local manufacturing capacity and the flexibility to supply a range of small molecule pharmaceuticals. Australia has historically invested heavily in influenza vaccine development and production. As a result Australia has one of the highest influenza vaccine capabilities in the world. By contrast, IDT is Australia's last small molecule API manufacturer and one of only a handful of local finished dosage form manufacturers.

Is Stockpiling Medicines The Best Way Forward?

Stockpiling has historically been the approach to address continuity of supply of critical medicines. The most obvious limitations to stockpiling of medicines is that medicines have a finite shelf life and demand pressures on certain medicines and medical products during this crisis showed how quickly global inventories can become depleted or in many cases exhausted. Also stockpiling is conceptually flawed in that no one can predict what medicine we will need for the next crisis. Retaining the facilities, skills and ability to manufacture critical drugs in a sovereign capacity would ensure a continued supply of medicine without reliance on opaque and fragile offshore supply chains.

Australia's Extant Pharmaceutical Manufacturing Capabilities

IDT has a facility that is capable of manufacturing a range of small molecule drugs and can also offer fill and finish surge capacity for a range of finished dosage form products. We would welcome a discussion on mapping and better understanding Australia's pharmaceutical supply chain and how Australia can best leverage its extant sovereign capabilities to reshape Australia's pharmaceutical supply chain post COVID-19.

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