SUBMISSION TO INQUIRY INTO THE IMPLICATIONS OF THE COVID-19 PANDEMIC FOR AUSTRALIA'S FOREIGN AFFAIRS, DEFENCE AND TRADE

30 JUNE 2020

Sanofi:

Sanofi is a leading global biopharmaceutical company focused on human health. We are dedicated to developing medicines and vaccines that extend and enhance the lives of millions of people around the world. We prevent illness with a large portfolio of paediatric and adult vaccines. We also save and change lives by developing and bringing to Australia innovative treatments across a range of therapeutic areas including oncology, immunology, speciality care, cardiovascular disease, diabetes, rare diseases and rare blood disorders.

In Australia, we employ around 700 people. Our corporate headquarters are in Sydney, with offices, state-of-the-art laboratories and a world-class manufacturing facility in Brisbane, as well as offices in Melbourne, Adelaide and Perth.

Globally, Sanofi has long-established leadership in vaccine technology and strong heritage in investment in basic research, both in small molecules and biologics. Two-thirds of Sanofi medicines and vaccines are on the WHO's list of essential medicines.

Since the start of the COVID-19 outbreak, Sanofi has been committed to the discovery, development, and delivery of critical medicines to meet this new global health threat. The company is studying some of our existing medicines as potential treatments for COVID-19 and leveraging our expertise to develop a new vaccine. Further, we are working on our manufacturing and supply capacities to anticipate demand and continue to supply our medicines to patients across the world.

Introduction:

It is timely for the Joint Standing Committee on Foreign Affairs, Defence and Trade to be conducting this inquiry into the implications of the COVID-19 pandemic on Australia's foreign affairs, defence and trade. Given Sanofi's expertise in the research, development, manufacture and supply of medicines and vaccines, our submission is focused on the issue of supply chain integrity as a critical enabler of Australian security from both a health and economic perspective.

As Medicines Australia states while "the medicines supply chain is complex, with multiple dependencies across sectors, nevertheless it is effective and efficient". Further, the link between the economic prosperity of the nation and maintaining a healthy and productive community has rarely been more evident than during the pandemic.

Throughout the COVID-19 pandemic, Sanofi worked collaboratively with the federal and state and territory governments, and their departmental representatives, with the goal of maintaining supply of prescription medicines on the Pharmaceutical Benefits Scheme (PBS), Life Saving Drugs Program (LSDP), National Blood Authority (NBA) and vaccines on the National Immunisation Program (NIP).

During March and April many of our prescription medicines and over-the-counter products saw significant increases above normal demand. For us to ensure supply and prevent stock-outs, we

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worked closely with the Therapeutic Goods Administration (TGA), Medicines Australia, Consumer Healthcare Products Australia, Complementary Medicines Australia, and wholesalers to manage our stock levels. In addition, there were two instances where export restrictions for over-the-counter products taken by foreign governments, namely India and Vietnam, paused our ability to import in supplies of paracetamol, paracetamol and codeine products, and ibuprofen manufactured in each respective location. However, through engagement with both the Australian government and diplomatic representatives we were able to resolve these issues and importation of these treatments occurred promptly thereafter.

Supply chain integrity:
While much of the world has gone into lockdown, Sanofi's global network of manufacturing plants have remained operational to help ensure continued supply of all Sanofi medicines and vaccines. However, increased government restrictions put in place by some countries during the pandemic have affected the flow of personal protective equipment and medicines (from raw materials to finished pharmaceutical forms). These measures have had a serious and immediate impact on the globally integrated supply chains that ensure quality, safety, innovation, and distribution of medicines and vaccines.

As solutions to COVID-19 become available, if trade restrictions were to continue, this would put at risk the integrity of global supply chains for medicines and vaccines. There may be other negative consequences arising from continued trade restrictions, including:

- Increased risk of supply shortages;
- Disruption of distribution channels;
- Interruption to clinical trials limiting early patient access to new medicines;
- Supply and demand imbalances; and
- Significant added supply chain management delays and costs.

Despite the rapid decline in cargo capacity (both sea and air) and global logistics slowdown due to reduced accessibility to ports, shipping containers, and labour forces resulting from COVID-19, Sanofi Australia has largely been able to overcome these challenges by working across our global industrial network to ensure continuity of supply of our medicines and vaccines to Australian patients. In addition, we worked collaboratively with our logistics partners to ensure they were prepared with COVID-19 business continuity plans.

Information to healthcare professionals and patients about stock-outs and out of stocks:
For some of our prescription medicines, we fielded many calls to our medical information line from Australian patients worried about being unable to fill their script at their local pharmacy. While we were able to manage these calls on a case-by-case basis, we believe there is an opportunity to improve co-ordination across stakeholder groups in future public health crises to limit unnecessary stockpiling of medicines and reduce the likelihood of spikes in demand. For example, access to information about medicines, which are not classified as out of stock but experiencing an increase in demand, would assist healthcare professionals and patients in locating and gaining access to their prescription at a pharmacy.

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In other jurisdictions technology solutions, such as 2D data matrix bar codes, designed to support anti-counterfeiting measures, also provide track and trace capabilities to follow the distribution of products in the supply chain from point of manufacture to the point of dispensing. This requires relevant infrastructure, including appropriate scanning devices and a centralised data warehouse, to be available. Other future technology solutions could provide options to link e-health record information for patients experiencing supply difficulties to personalised notifications about supply locations in their area. These options would be invaluable in managing communication in an increasingly e-health environment. Exploration of such opportunities requires a cross departmental approach to innovation, technology and regulation to create an Australian-wide infrastructure, digital network and regulatory framework to transform current ways or working.

Influenza vaccine supply:
Manufacturing vaccines is a complex and costly process. Depending on the vaccine being produced, it can take between 6 to 36 months to produce, package and deliver high quality vaccines to those who need them. This includes testing each batch of vaccine at every step of its journey, and repeat quality control of batches by different authorities around the world and final quality release testing by the TGA. In fact, 70% of production time is dedicated to quality tests.

In relation to influenza vaccines, we were pleased to be able to fulfil our public and private market orders for the 2020 influenza season, despite the increased demand resulting from COVID-19. We were able to achieve this because vaccine orders were placed by October 2019, which allowed our manufacturing facilities, located in the northern hemisphere, enough time to acquire sufficient antigen to develop and conduct quality tests of the vaccine. Due to the length of vaccine production, it is imperative that accurate forecasting for influenza vaccines occurs in the year prior to use to ensure there is enough supply to meet demand. It is also important that the price paid by the federal government for vaccines listed on the NIP more accurately reflects the true cost of developing and manufacturing vaccines, as this would contribute to a more viable vaccine industry. This, in turn, would reduce the likelihood of supply constraints at times of market stress, such as global pandemics.

Recommendations for future pandemic preparedness:
Sanofi believes there are several actions the federal government could consider to support the integrity of the supply chain and keep consumers informed about medicines supplies, including:

- National co-ordination of medicines and vaccines supplies across states and territories, including public hospitals, to enable equitable distribution and dispensing from hospital and retail pharmacies;
- Federal government to establish a taskforce to assess opportunities for utilisation of connected e-health data and technology solutions to support better collection and sharing of information on medicine and vaccines experiencing stock shortages and stock-outs;
- Better alignment of the price paid by the federal government for vaccines listed on the NIP with the cost and effort required to research and develop new vaccines; and
- Maintain regular meetings of the various government taskforces, such as logistics, to ensure the framework and governance is maintained in the event of another pandemic.

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