RESPONSE TO SENATE SELECT COMMITTEE ON COVID-19
28 MAY 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. We are proud to have invested $40 million in our consumer healthcare manufacturing centre in Brisbane in recent years.

At both the local and global level, Sanofi's decision-making is grounded in putting the needs of the patient first. This commitment extends to ensuring timely and affordable patient access to our medicines and vaccines.

COVID-19 and access to Sanofi treatments:
Our commitment to working collaboratively with Australian federal, state and territory governments, and their departmental representatives, has remained steadfast as we have worked to respond to the unprecedented health crisis of COVID-19 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).

Sanofi has maintained ongoing dialogue with the Department of Health and Offices of the Minister for Health, Office of the Minister for Industry, Science and Technology, and other relevant ministerial colleagues, as required, to respond to the government's emerging needs and those of our customer. We have also worked with our logistics partners to ensure they were prepared with COVID-19 business continuity plans.

We have undertaken the following activities to support business continuity across our portfolio and to ensure equitable market access to our products:

- Working across our global industrial network to support supply of our medicines and vaccines to Australian patients;
- Working constructively with the Australian government and diplomatic representatives to overcome the export restrictions placed on our paracetamol products, manufactured in India, by the Indian government;
- Working constructively with the Australian government and diplomatic representatives to overcome the export restrictions placed our ibuprofen products, manufactured in Vietnam, by the Vietnam government;

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- Proactively engaging with the Therapeutic Goods Administration (TGA) to share information on medicines supply and fast track any approvals required to avoid medicines shortages;
- Establishing a Sanofi local response team to work closely with the TGA, Medicines Australia, medicines wholesalers and patient groups to specifically manage supply of hydroxychloroquine to ensure access for those who rely on this treatment to manage the chronic conditions for which this product is TGA approved, including engaging in discussions with Generic Biosimilar Medicines Association (GBMA) members in order to maintain continuity of supply under the Interim Authorisation granted by the Australian Competition and Consumer Commission (ACCC);
- Working with the TGA and professional societies to circulate a Dear Healthcare Professional (HCP) Letter to highlight the risks of off-label use and reinforce the importance of new prescribing restrictions to maintain enough supplies for patients on existing therapies;
- Supporting patients and HCPs through our dedicated customer service and medical information teams, as well as managing an unprecedented volume of calls to ensure patients could access the medicines they need;
- Addressing concerns from patient groups and HCPs about the potential risks of use of hydroxychloroquine for patients on Fabry treatment (Fabryzyme©) and Pompe treatment (Myozyme©) to ensure their safety; and
- Negotiated a formal commitment from home infusion providers to increase capacity and move hospital infused Fabry and Gaucher patients to home infusion on request.

In addition, Sanofi's work with Medicines Australia has helped to ensure communication lines between industry, healthcare professionals, and most importantly patients, have remained open and efficient at this critical time. This included a roundtable jointly hosted by Medicine Australia, the TGA and Consumers Health Forum of Australia (CHF) for patients and consumers on the topic of the medicines and vaccine supply chain.

The global logistics slow down due to accessibility to ports, shipping containers, and labour forces added to the potential for our treatments to become limited or out-of-stock in the country. This presented critical supply challenges to Sanofi Australia and required an urgent coordinated response through the functional teams within our business. In most cases, we managed to overcome or alleviate these incoming goods supply issues by synchronising our efforts:

- Using our long-standing supplier relationships to highlight Sanofi Australia's commitment to and prioritisation of our supply;
- Our specialist logistics team using Sanofi freight partners to assist suppliers with dispatch options;
- Fast-tracking internal approval processes for rapid freight release (e.g. air freight, alternate sea freight);
- Co-ordination of activities with our Australian manufacturing facility, Supply Chain, Production and Quality teams to maximise output for our consumer healthcare products based on raw material availability; and
- Early escalation to the relevant Minister's offices and then to the subsequent TGA supply Taskforce, Department of Foreign Affairs and Trade (DFAT) Coronavirus Coordination Team and the Freight Taskforce.

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Continuation of clinical trials:
The continuation of clinical trials through this period remained an imperative to ensure patients maintained access to ongoing trials for a broad range of disease areas. Any delay in the ongoing recruitment, commencement of clinical trials or disruption to clinical trials had the potential to delay access to new and innovative treatments. As a result of our quick action, Sanofi's clinical trials in Australia were able to proceed with minimal disruption due to COVID-19; with only a few sites forced to close due to specific site limitations. The steps we took to ensure the continuation of clinical trials included:

1. **Direct to patient study medication shipments**: normally a patient would collect their study medication from the trial site pharmacy. However, with many sites being closed to patient study visits, where necessary we implemented a process whereby our existing drug distribution vendor could deliver the study medication directly to the patient's home. This ensured continuation of study treatment for patients in cases where the medication was not an infusion.
2. **Remote monitoring visits:** as most of our hospital sites are closed to on-site monitoring visits from Clinical Research Associates (CRAs), each study has implemented a risk-based approach, where study data and milestones have been considered. Remote monitoring visits via telephone have been initiated to ensure CRA oversight, patient safety and data integrity has been maintained.
3. **Working closely with our sites to be partners and ease their load:** we understand that hospital sites are under enormous pressure, so we have supported them with novel initiatives wherever possible, including:
    a. Scenarios where we have arranged for a CRA to have remote access to the electronic medical records to continue source data verification and patient oversight for a phase I study (with the required global and data privacy approvals);
    b. Arranging for a courier service to transport blood samples to the hospital laboratory when a site needed to set up at a satellite location so that immunocompromised patients did not need to attend the hospital; and
    c. Arranging for patient diaries for a study to be included in the direct to patient medication shipment to save the site sending these separately.

Adaptation and agility from office work to home office:
Globally, Sanofi's executive committee and crisis committee asked employees who were able to work from home to do so from 17 March 2020. In Australia, this meant that we enacted the direction prior to physical distancing measures announced by the Australian Government. At the same time, we took action to protect the health of business-critical teams who have continued to go to work sites around the world, including Australia (see Australian manufacturing for more information on this point).

In Australia, a local COVID-19 committee was formed with senior leaders, including Human Resources, Health, Safety and Environment, Communications and Medical, to manage the situation and ensure employees could be kept abreast of relevant information. This included the establishment of dedicated COVID-19 online and social content for employees, as well as all-employee webinars providing medical and health and safety information from our in-house experts.

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Sanofi Australia employs people across most Australian states and territories, and those people's roles can include the need to interact with front line healthcare workers so any decision to return to our workplaces will only be made in strict accordance with national and state guidance. We are continuing to monitor Australian Government guidelines and safeworkaustralia.gov.au as we plan for the future of our workplaces.

Australian manufacturing:
Sanofi Consumer Healthcare brands are diverse, including over-the-counter pharmacy medicines through to vitamin and mineral supplements (VMS), the latter of which are made at our Virginia manufacturing plant. With a heritage, in some instances, spanning more than 70 years in Australia, many of our brands are household names, including Cenovis©, Nature's Own© and Ostelin©. These products make up approximately 12% of the Australian nutritionals market across grocery and pharmacy outlets, making them important contributors to consumer healthcare in this market. In addition to this robust domestic market, the Virginia plant also supplies a growing export business, largely to China and South Korea, valued at over $66M in retail sales per annum.

Sanofi's manufacturing plant adheres to stringent internal and external quality control processes, using state-of-the-art analytical equipment. We use our international network to source high quality raw ingredients from Australia and around the globe. We also manufacture according to the Pharmaceutical Inspection Convention and the Co-operation Scheme Guide to good manufacturing practice for medicinal products.

Our manufacturing plant is run by a team of highly skilled professionals, which includes research and development, quality control, manufacturing, distribution, regulatory affairs, marketing and other specialists. Of the 200 staff based in our Virginia site, 20 people out of 200 can be classed as non-critical, requiring 180 people to be on-site producing products. The two primary processes still occurring on-site are:

1. Production: these roles occur in full Good Manufacturing Practices (GMP) gowning following validated practices, including cleaning and sanitation. In addition, staff members on the production lines required to work in close proximity adhere strictly to physical distancing rules; and
2. Research and development: this includes formulating and developing new and repatriation products, troubleshooting existing product formulations and assessment of new raw materials. These roles also occur in full GMP gown and sanitisation.

In order to provide a safe workplace for staff remaining on-site and remain consistent with physical distancing rules outlined by the federal government we:

- Implemented temperature checking of all staff at arrival to site, including permanent, casual and third-party contractors (averaging 180 checks per day);
- Introduced strict physical distancing measures at site, including removal of over 50% of the seating and tables in the café;
- Separated remaining office staff and enforced distancing within the manufacturing facility;
- Increased the availability of hand sanitiser at key locations throughout all facilities and increased the education to all staff on the importance of good hand hygiene; and

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- Have substantially increased cleaning and sanitation of surfaces outside of the GMP facility, in line with Global Sanofi guidance (GMP facility already covered by GMP requirements including micro-testing).

Conclusion:
By working collaboratively with our internal and external stakeholders, including the Australian federal, state and territory governments, their departmental representatives, and business partners, we have managed to minimise disruption resulting from COVID-19. Ultimately, this has meant Australians who rely on our medicines, vaccines, VMS and consumer healthcare products have largely continued to receive access to these products throughout the pandemic. Similarly, for therapies at the clinical trial stage, Australians have generally been able to continue to receive access to what can be life-saving medicines.

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